Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired: 1-800-735-2466 VOICE: 1-866-735-2460

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

June 1, 2018

Janice Thomas, VP of Patient Services & Research
Reproductive Health Services/
Planned Parenthood of the St Louis Region and Southwest Missouri
4251 Forest Park Ave, St. Louis MO 63108

Regarding Applications as Abortion Facilities for:

Springfield Planned Parenthood Clinic
626 East Battlefield
Springfield MO 65807

Joplin Planned Parenthood Clinic
710 Illinois Avenue
Joplin MO 64801

Janice Thomas:

1. During an interview on 5/29/2018 and confirmed on 5/30/18, St. Louis Planned Parenthood administrative staff stated that current plans to license the Springfield and Joplin locations as Abortion Facilities were indefinitely on hold.

2. By convention, the Bureau of Ambulatory Care holds applications open for new facilities for up to one year before requiring a new application package be submitted. The applications for the Springfield and Joplin locations were received by the Department of Health & Senior Services on 5/25/17, just over one year ago.

3. An initial inspection for the Springfield location was conducted October 2017. To date, an acceptable plan of correction for the items cited during that inspection has not been received. Moreover, a complete set of revised rules for abortion facilities went into effect on 4/30/2018, which would require a new inspection.

Due to the above items, the Bureau of Ambulatory Care is hereby closing the open Abortion Facility applications for the Springfield and Joplin Planned Parenthood Clinics. You may submit new applications at any point you believe the facilities are prepared to be in compliance with all applicable laws and rules for Abortion Facilities in Missouri.

If you have additional questions, do not hesitate to contact our office via email at BAC@health.mo.gov or by phone at 573-751-6083.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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If you have additional questions, do not hesitate to contact our office via email at BAC@health.mo.gov or by phone at 573-751-6083.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Release and Settlement Agreement

This Release and Settlement Agreement is made and executed by and between Planned Parenthood of Kansas and Mid-Missouri, Inc., (hereinafter referred to as "PPKM"), the Missouri Department of Health and Senior Services, (hereinafter referred to as "DHSS"), Margaret Donnelly, in her official capacity as the Director of DHSS (hereinafter referred to as "Donnelly"), Chris Koster, in his official capacity as Attorney General of the State of Missouri (hereinafter referred to as "Koster"), James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, Missouri (hereinafter referred to as "Kanatzar"), and Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, Missouri (hereinafter referred to as "Knight"), (DHSS, Donnelly, Koster, Kanatzar, and Knight will hereinafter be referred to collectively as "Defendants"; PPKM and Defendants will hereinafter be referred to collectively as the "Parties.") The Parties enter into this agreement through their respective lawyers.

For due and good consideration recited herein, the Parties agree and state as follows:

1. **Plaintiff.** PPKM is the Plaintiff in lawsuits styled (1) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Jane Drummond, et al.*, No. 07-4164-CV-C-ODS, in the United States District Court for the Western District of Missouri, Central Division; (2) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00463, filed in the Cole County Circuit Court; and (3) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00276, filed in the Cole County Circuit Court.

(These lawsuits will hereinafter be referred to collectively as the "Lawsuits.")

2. **Defendants.** Defendants are named as the defendants in the Lawsuits.

3. **Scope of Agreement.** This Agreement embodies the entire agreement and understanding of the Parties with respect to the subject matter contained herein. The Parties hereby declare and represent that no promise, inducement, or agreement not herein expressed has been made, and the Parties acknowledge that the terms and conditions of this Agreement are contractual and not a mere recital.

4. **Non-Admission.** No actions taken by the Parties, or any of them, either previously or in connection with this Agreement shall be deemed or construed to be an admission of the truth or falsity of any matter pertaining to any claim or defense alleged in the pleadings filed on behalf of the Parties in the Lawsuits, or an acknowledgment by any of the Parties of any liability to the other parties or to any person for any other claim, demand, or action, all liability being expressly denied by the Parties.

5. **Consideration.** In consideration for (1) PPKM's dismissal of the Lawsuits; (2) PPKM's release of claims as set forth in paragraph 10 of this Agreement; (3) PPKM's agreement to complete structural changes at the Columbia Center and to otherwise comply with 19 CSR 30-30.070(2), as set out in paragraph 6 of this Agreement; and (4) PPKM's agreement that the Brous Center will comply with certain provisions of 19 CSR 30-30.050 and 19 CSR 30-30.060, as set out in paragraph 7 of this Agreement, the Defendants agree that DHSS will approve the Columbia Center and the Brous Center for licensure as abortion facilities.

6. **Modifications of the Columbia Center.** PPKM agrees to make modifications to its facility located in Columbia, Missouri ("Columbia Center") as set out in the attached Addendum A. PPKM anticipates being able to begin construction within nine months of the date that this Agreement is finally signed by all the parties and completing construction within sixteen months from the date this Agreement is finally signed by all the parties, and agrees that while certain factors relevant to this timing (such as the DHSS's approval of its architectural drawings and sprinkler plans) are not under PPKM's control, it will make a good-faith effort to comply with these time frames.

PPKM agrees that it will submit architectural drawings showing the modifications to be made, as set out in Addendum A, to DHSS before work begins at the Columbia Center, including the agreed upon modifications in the sterilization and soiled rooms, and the sprinkler plans. PPKM agrees that DHSS shall be granted entry onto the Columbia Center premises for a mid-construction progress inspection. DHSS agrees that it will give PPKM at least 7 days prior notice of the proposed date for its progress inspection, which shall commence at an agreed upon date and time convenient to both parties. DHSS will be available for follow up questions and approval of specific construction or design questions as they arise and will endeavor to provide prompt responses to the Columbia Center during the construction and pre-approval phases.

PPKM agrees to permit DHSS to conduct a final inspection of the Columbia Center within 2 weeks of the completion of the structural modifications set out in Addendum A and before an abortion facility license is issued to ensure that the modifications at the Columbia

Center have been completed as agreed and also to ensure that the Columbia Center is also in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A. If this inspection reveals that the modification set out in Addendum A have not been completed as agreed, or that the Columbia Center is not in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, PPKM agrees that it will make a good-faith effort to complete the remaining work needed for the Columbia Center to complete the modifications set out in Addendum A, and to be in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, within six weeks.

DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the requirements of 19 CSR 30-30.070(2) except as specifically set forth in Addendum A, and will not require changes not set forth in Addendum A unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to no longer be in compliance with those requirements.

7. **Brous Center.** PPKM will comply with the procedural, operational, and management requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, at its Brous Center location. Modifications to certain requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060 that will apply to the Brous Center are set forth in Addendum B.

PPKM agrees to permit an inspection of the Brous Center before an abortion facility license is issued to ensure that the Brous Center is in compliance with the requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, as modified by Addendum B.

The Parties acknowledge that the Brous Center currently does not perform surgical abortions. If the Brous Center at a future time wishes to provide surgical abortion services, PPKM will notify Defendants' counsel. PPKM understands that the performance of surgical abortions at the Brous Center would constitute a material change that would require the Brous Center to comply with additional regulations.

8. **Provision of Services.** It is the intention of the Parties and Defendants that the Columbia Center may continue providing abortion services throughout the process of preparing for and completing the modifications described in paragraph 6, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process. It is the intention of the Parties and Defendants that the Brous Center may continue providing medication abortion services during the abortion facility license application process, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process.

9. **Dismissal of the Lawsuits.** Upon payment of the fees and expenses set forth in Paragraph 12 of this Agreement, the Parties shall also execute the following Stipulations of Prejudicial Dismissal: (a) a Stipulation of Prejudicial Dismissal pursuant to Fed. R. Civ. P. 41(a)(1)(ii), to be filed the federal lawsuit identified in paragraph 1 of this Agreement, dismissing with prejudice PPKM's claims in their entirety; and (b) Stipulations of Prejudicial Dismissal pursuant to Mo. R. Civ. P. 67.02, to be filed in the state lawsuits identified in paragraph 1 of this Agreement dismissing with prejudice all claims raised in those lawsuits.

10. **Release.** PPKM does hereby release, acquit, and forever discharge the

Defendants, the State of Missouri, and any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, of all and from any and all liability, claims, actions, causes of action, demands, rights, damages, costs, interest, loss of service, expenses, and compensation whatsoever, whether or not now known or contemplated, which PPKM now has, or which may hereafter accrue, against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on or arising out of the allegations in the Lawsuits relating to the licensure of the Columbia and Brous Centers. PPKM specifically acknowledges that it is forever barred from filing suit against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on any claim based on or arising out of the allegations in the Lawsuits relating to licensure of the Columbia and Brous Centers.

11. **Full Consideration.** PPKM acknowledges that the consideration described in paragraph 5 of this Agreement is all that it or its representatives are ever to receive from the State of Missouri, the Defendants, or any person or entity related to them whatsoever, for the settlement described in this Agreement, whether in settlement of PPKM's claims for damages, attorney's fees, costs, or other claims which were or could have been asserted in the Lawsuits.

12. **Attorney's Fees, Costs and Expenses.** In exchange for payment of $80,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and the regulations implementing that law to the

Columbia Center, and payment of $65,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and regulations implementing that law to the Brous Center in the federal lawsuit, PPKM hereby waives any remaining claim it might have against the State of Missouri, the Defendants in the Lawsuits, or any current or former employee, agent, agency, actor, or contractor of the State for attorney's fees, expenses, or costs, pursuant to 42 U.S.C. § 1988, or any other statute, rule, or other provision of law which is or may be in any way applicable hereto. The payment of $145,000.00 will be issued to Plaintiff's counsel by June 30, 2010.

13. **Court Costs.** The Parties will bear their own court costs.

14. **Non-Assignment.** PPKM hereby represents, acknowledges, and warrants that it has not at any time heretofore assigned to any other person or entity all or any portion of any claim or potential claim whatsoever that it may have, or may have had, against the Defendants, the State of Missouri, or any person or entity whatsoever based on or arising out of the allegations contained in the Lawsuits.

15. **Binding Effect.** The persons signing this Agreement represent that they have read this Agreement and fully understand its provisions. The signatories of the Parties declare that they are of legal age and that they have relied solely upon their own judgment without influence of anyone in making this Agreement. This Agreement shall be binding upon, and inure to the benefit of the heirs, personal representatives, successors, and assigns of the Parties.

16. **Preparation of Documents.** This Agreement is the joint work product of the

Parties and, in the event of any ambiguity herein, no inference shall be drawn against a party by reason of document preparation.

17. **Further Execution.** Each party hereto shall execute any and all documents as are necessary or desirable to consummate the transactions contemplated hereby.

18. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be deemed executed as of the date the Agreement was finally signed by the Parties below.

PLANNED PARENTHOOD OF KANSAS
AND MID-MISSOURI, INC.

By: _____

Title: Attorney for PPKM

STATE OF New York)
) ss
COUNTY OF New York)

Before me, a notary public for the State of New York, personally appeared Jonn for Sandmann, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Planned Parenthood of Kansas and Mid-Missouri, Inc., and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18 day of May, 2010.

_____
Notary Public

My commission expires on 11/9/13.

DARA KLASSEL
NOTARY PUBLIC-STATE OF NEW YORK
No. 02KL4913955
Qualified In New York County
My Commission Expires 11/9/13

MISSOURI DEPARTMENT OF HEALTH
AND SENIOR SERVICES

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF Missouri)
) ss
COUNTY OF Cole)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for the Missouri Department of Health and Senior Services with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08500003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

MARGARET DONNELLY, in her official capacity as Director, Missouri Department of Health and Senior Services

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Margaret Donnelly with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Margaret Donnelly, in her official capacity as Director of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08500003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012

CHRIS KOSTER, in his official capacity as Attorney General of Missouri

By: Emily A. Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Chris Koster with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Chris Koster, in his official capacity as Attorney General of Missouri, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number 08451008

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

JAMES KANATZAR, in his official capacity as Prosecuting Attorney of Jackson County

By: _____

Title: Prosecuting Attorney

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared James F. Kanatzar, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 26 day of May, 2010.

_____
Notary Public

My commission expires on _____.

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

MICHAEL A. WELLS
My Commission Expires
September 24, 2012
Jackson County
Commission #08499225

DANIEL KNIGHT, in his official capacity as Prosecuting Attorney of Boone County

By: Charles J. Dykhouse

Title: County Counselor for Boone County

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Charles J. Dykhouse, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18th day of May, 2010.

DEBORAH A. SPRAGUE
Notary Public - Notary Seal
State of Missouri
County of Boone
My Commission Expires August 10, 2012
Commission #08379045

Deborah A. Sprague
Notary Public

My commission expires on August 10, 2012.

ADDENDUM A

Work to Be Completed by Planned Parenthood of Kansas and Mid-Missouri at its Columbia Center as Described in Paragraph 6 of the Settlement Agreement

Corridors and Patient-Traveled Doors

In light of the Columbia Center's specific configuration, the Department determines that the facility's existing corridor width of 5 feet and door widths and construction are acceptable if combined with the following modifications. The door swing in the procedure and recovery rooms will be made so that they continue to swing into the room, but swing next to the wall and out of the way of the gurney. The fire extinguisher on the wall opposite the recovery room will be moved to the same side as the recovery room. The fire extinguisher adjacent to the procedure room will be moved to the same side as the procedure room. These modifications will provide extra maneuvering room for a stretcher into either room.

Construction Type/Sprinkler System

The Regulations require single story facilities to be Type II (111) construction. The facility will become fully equipped with a sprinkler system, which will be an acceptable alternative to the construction type. The design specifications for the sprinkler system must be submitted to the Department for approval before construction begins.

Dimensions for procedure room

The Regulations require the procedure room to be 12 feet length and width and a minimum ceiling height of 9 feet. The procedure room to be used by the Columbia Center is

12 feet by 9 feet, 1/2 inch, with a ceiling height of 8 feet, 6 inches. These dimensions are an acceptable alternative because the facility will only use one procedure room.

Personnel Change Rooms

The Regulations require personnel change rooms for each sex, be located convenient to the procedure room, and each equipped with a toilet and lavatory. The facility may have only one, unisex personnel change room because the facility will only use one procedure room.

Procedure Room Lighting

The Regulations require that the procedure room be equipped with a ceiling-mounted surgical light. The Department grants a deviation from this Regulation to the Columbia Facility provided that the procedure room be equipped with a wall-mounted surgical light and gooseneck light.

Patient Change Rooms

The Regulations require at least two patient change rooms with storage for personal effects. The facility shall be allowed to use only one patient change room and to have patient belongings travel with the patient in a secure container, if it uses only one procedure room and does not use the procedure room as the change room.

Counseling Room Dimensions

The Regulations require that counseling rooms shall be separate and not smaller than ten feet by ten feet (10' x 10'). The facility shall be allowed to use its counseling room that is eight feet by ten feet, eleven inches (8' x 10', 11'').

Scrub Facility

The Regulations require knee or foot-operated scrub facilities located immediately outside the procedure room. The Facility shall be allowed to use a hands-free scrub sink located in the former procedure room which will no longer be used as a procedure room, and which is adjacent to the usable procedure room.

Sterilizing Room

The Facility shall provide a sterilization room with positive air pressure in relation to adjacent areas, in accord with 19 CSR 30-30.070(2)(v). The Facility shall also provide a separate soiled/decontamination room with a constant running exhaust.

Additional Items:

The following items shall also be completed:

The facility shall install five (5) additional exit signs to clearly indicate the direction of exit travel.

The facility shall make ceiling tile in the clinical area so that it is smooth and easily cleanable.

The patient toilet facility shall be equipped with a constant running exhaust.

All open cabinet storage of supplies in the procedure room must be converted into closed cabinets in accord with the Regulations.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.070(2) shall apply in full to the Columbia Center. DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the

requirements of 19 CSR 30-30.070(2) except as specifically set forth above, and agrees that it will not require changes not set forth in above unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to be no longer in compliance with those requirements.

ADDENDUM B

Modifications of Brous Center requirements.

The Brous Center's quality assurance program will review all medication abortion complications, but will not be required to review the following items set forth in 19 CSR 30-30.060(3)(J) that are not applicable to medication abortion: cases that resulted in a stay of more than twelve (12) hours, and cases in which gestational age was determined to be beyond eighteen (18) weeks. The quality assurance program will not be required to review intraoperative and postoperative complications, however, complications of medication abortion, including incomplete or failed medication abortions that requires surgical completion, and hemorrhaging that requires surgical intervention following a medication abortion, shall be reviewed as part of the quality assurance program.

The Brous Center will not be required to provide medication abortion in a procedure room or a recovery room, and requirements that relate to the procedure and/or recovery room are therefore inapplicable. Continuous physician services or registered professional nursing services will be provided whenever an abortion patient is in the Brous Center, once the patient has received the mifepristone or other medication that begins the abortion process. PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060 (3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)(4). 19 CSR 30-30.060(3)(H)(2) and 19 CSR 30-

30.060(4) (A) through (C) do not apply to the inducement of medication abortions at the Brous Center.

The Brous Center will provide Anti-Rh immune globulin therapy to Rh negative patients during the appointment where the patient receives the mifepristone or other medication that begins the abortion process. The Brous Center need not perform urinalysis or a pelvic exam for every abortion patient, because it performs ultrasound on every patient to confirm pregnancy and gestational age. It will also perform hematocrit or hemoglobin and RH typing on every abortion patient. The option to perform a hemoglobin test instead of a hematocrit shall apply to the Columbia Center as well as the Brous Center.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.050 and 19 CSR 30-30.060 shall apply in full to the Brous Center.

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 18, 2016

Via email to abenson@bensonlaw.com

Arthur Benson
Arthur Benson & Associates
4006 Central Street
Kansas City, Missouri 64111-2236

Re: Comprehensive Health of Planned Parenthood Great Plains – Kansas City and Columbia facilities

Dear Mr. Benson:

This is in response to your November 11, 2016, letter to me regarding physician privileges at the Kansas City and Columbia, Missouri Planned Parenthood facilities.

Regarding physician privileges at the Kansas City facility, the 2010 settlement agreement states (page 19), "PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060(3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)4."

Your letter states that the Kansas City facility has a physician with surgical privileges at Overland Park Regional Medical Center who would provide medication abortions. Such privileges do not comply with the settlement agreement. Until the facility is in compliance with the privileges requirement of the settlement agreement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Regarding the Columbia facility, your letter states that the facility "has secured a written transfer agreement with a hospital within 15 minutes' travel time" from the facility "which fulfills 19 CSR 30-30.060(1)(C)(4)."[1] The department has not received a copy of this agreement and is therefore unable to confirm whether it complies with the regulation. Regardless, the facility still must comply with 19 CSR 30-30.060(1)(B)12, which states, "The administrator shall be responsible for ensuring that the provisions of Chapter 188 RSMo, Regulation of Abortions, are adhered to." Sections 188.027 and 188.080, RSMo,

[1] Regulation 19 CSR 30-30.060(1)(C)4 states, "Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility."

require that all physicians performing or inducing abortions have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced. Neither of the facility's two physicians have the required privileges. Until the facility is in compliance with the privileges requirement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Additionally, page two of your letter states, "A number of the remaining items you identified with respect to the Columbia facility seem far from a basis on which to deny licensing." To be clear, the department has not denied licensure; the department has identified the deficiencies that must be corrected before licensure could be granted.

If you have additional questions, you may contact our office at (573) 751-6083 or via email at the address below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

August 11, 2017

Amanda Addison (Amanda.addison@ppgreatplains.org)
Comprehensive Health of Planned Parenthood Great Plains
1001 Emanuel Cleaver II
Kansas City, MO 64110

Re: Comprehensive Health of Planned Parenthood Great Plains – Kansas City survey

Dear Ms. Addison:

The Department received the application for licensure of the Kansas City Planned Parenthood location (Brous Center) as an abortion facility. Department staff conducted an onsite survey of the facility on October 19, 2016 to determine compliance with the terms of the 2010 settlement agreement and applicable statutes and regulations. In a letter to the facility dated November 2, 2016, the Department identified the items that were not in compliance.

After the facility submitted a complete response and documentation regarding correction of the items that were not in compliance, the Department performed an onsite revisit of the facility on July 27, 2017. At the time of the revisit, the Department determined that the facility is in compliance with current legal requirements for licensure.

The abortion facility license is attached, effective date August 11, 2017.

If you have further questions, you may contact our office at 573-751-6083 or via email at the address noted below.

Sincerely,

John Langston

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A005	A. BUILDING: _____ B. WING _____	R 07/27/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	1001 EMANUEL CLEAVER II BLVD KANSAS CITY, MO 64110

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments On onsite, unannounced revisit survey was conducted on 07/27/2017 to follow up on items originally cited during the 10/19/16 inspection. The revisit was delayed due to ongoing legal action following the 10/19/16 inspection. Results of the 07/27/17 revisit indicate that the facility is now in compliance with applicable sections of 19 CSR 30-050 and 30.060 as well as the terms of the 2010 settlement agreement and applicable statutes.	{L 000}		

Hoffmann, Tracy

From: Langston, John
Sent: Wednesday, December 20, 2017 8:07 AM
To: Hoffmann, Tracy
Subject: FW: KC facility complication plan approval
Attachments: PPGP proposed complication plan updated 102717 - KC 4pm.pdf; PPGP - Brous complication plan attachments - 10.26.2017 updated.pdf

Print and then scan the email from Nikki as well as the attachments as one document to put on the O-drive as description "DHSS-approved complication plan for PPGP-Kansas City to comply with SB5. Approved 10/27/2017."

From: Loethen, Nikki
Sent: Friday, October 27, 2017 5:18 PM
To: Linneman, Dean; Creach, Julie; Koebel, William; Langston, John
Subject: FW: KC facility complication plan approval

From: Loethen, Nikki
Sent: Friday, October 27, 2017 4:57 PM
To: diana.salgado@ppfa.org
Subject: KC facility complication plan approval

Diana,
This email serves as the department's written approval for the attached complication plan (including attachments) for the KC facility.
Nikki

Nikki Loethen
General Counsel
Department of Health & Senior Services
912 Wildwood Drive
Jefferson City, MO 65102
Phone: 573.751.6005
Fax: 573.751.0247

From: Salgado, Diana [mailto:diana.salgado@ppfa.org]
Sent: Friday, October 27, 2017 3:59 PM
To: Loethen, Nikki
Subject: Re: FW: Comprehensive Health of PPGP's complication plan

Nikki -

We made the final edits you requested to the Kansas City ("Patty Brous") health facility's complication plan. Please confirm that the plan has been approved by the Department.

Thank you.

Diana O. Salgado
Senior Staff Attorney
Public Policy Litigation & Law
Planned Parenthood Federation of America
212-261-4399

Americans
United
for Life

PLANNED PARENTHOOD GREAT PLAINS – PATTY BROUS

Department of Health and Senior Services Complication Plan

DIVISION:	Health Services	**EFFECTIVE DATE:**	October 27, 2017
WORK PRACTICE:	DHSS Medical Abortion Complication Plan	**NUMBER OF PAGES:**	2
DOCUMENT RELATED TO:	Senate Bill 5		

I. Purpose

This plan is submitted in order to comply with Senate Bill 5 (HCS for SS for SB5, 99th General Assembly, Second Extraordinary Session (2017)). Pursuant to SB5, facilities licensed to perform abortions must have in place a complication plan that meets certain standards.

II. Facility Physicians

This plan applies to PPGP's licensed abortion facility in Kansas City (the Patty Brous facility). The physician performing medication abortions in Kansas City (Dr. Ronald Yeomans, M.D.) is board-certified by the American Board of Obstetrics and Gynecology. In addition to this physician, PPGP's Medical Director (Dr. Orrin Moore, M.D.) is a board-certified OB/GYN. Both of these OB/GYNs have admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center. As the Medical Director, Dr. Moore shall personally treat complications 24/7 relating to medication abortions, including by providing surgical follow-up care. If Dr. Moore is ever unavailable to treat complications, Dr. Yeomans will treat complications 24/7 during the time that Dr. Moore is unavailable.

III. Treatment of Complications

PPGP maintains an answering service for which a nurse (RN, LPN, or NP) is on call 24/7 to address patients' questions and concerns. A board-certified OB/GYN physician is available to the on-call nurse 24/7 to respond to questions and determine plan of care, if necessary.

Patients who have a medication abortion must receive written post-abortion care instructions that:

- provide signs and symptoms of problems to watch for;
- instruct patients on what to do if a problem occurs, including when to contact the on-call nurse; and
- provide the phone number of the answering service to reach the on-call nurse.

When a patient calls the 24/7 answering service, the call will be forwarded to the on-call nurse. The on-call nurse must be trained to assess each patient individually and identify and manage problems the patient may be experiencing, in accordance with established protocols.

After the patient is personally assessed, and if the on-call nurse and/or the on-call OB/GYN physician determines that follow-up care is needed, the patient will be directed to return to a health center to receive such care. If a patient requires follow-up care from a physician, Dr. Moore will

personally treat complications relating to medication abortions, including those requiring surgical follow-up care, which were provided to patients at the Patty Brous facility.

However, if after the patient is personally assessed and if the on-call nurse and/or Dr. Moore determines that it is not in the patient's best interest or it would not be in accordance with the standard of care for the patient to receive follow-up treatment from Dr. Moore, the patient will be instructed to go to her nearest emergency room. The patient must be instructed to take with her to the emergency room the written take-home instructions that were previously provided to her, which explain that the patient received abortion care, and encourages the emergency room to contact the 24/7 answering service. The patient must also be instructed to call the on-call nurse once she arrives at the emergency room.

The on-call nurse must not, as a matter of course, call the emergency room in advance without the patient's consent in order to protect her confidentiality and privacy, as the patient may decide to go to a different hospital for a variety of reasons (such as financial issues, insurance coverage, or concerns about confidentiality).

Once the patient arrives at the emergency room, she or, with the permission of the patient, the attending physician or other clinician managing her care should call the PPGP on-call nurse so that the attending physician or other clinician managing the patient's care can be briefed on the care the patient received.

On-call nurses document each call, including those that do not involve complications, and enter notes into patient records. The on-call nurses maintain communication with each other regarding patients who were assessed and require follow-up care.

IV. Follow-up Care

In the event the on-call nurse advises a patient to seek emergency care, a follow-up call is made by PPGP to that patient within 24 hours. The follow-up call is to be documented in NextGen.

V. Reporting

The OB/GYN treating a patient's complication shall prepare a complication report as required by § 188.052, RSMo, and ensure that the report is submitted to the Missouri Department of Health and Senior Services and placed in the patient's medical record.

VI. Covered Physicians

The PPGP physician covered by this plan is Dr. Ronald Yeomans, M.D. The OB/GYN providing 24/7 back-up complication coverage is Dr. Orrin Moore, M.D. A copy of the written agreement between PPGP and Dr. Moore is attached to this plan, along with a copy of Dr. Moore's and Dr.

Department of Health and Senior Services Complication Plan

Yeomans' OB/GYN board certification credentials profiles.

Memorandum of Understanding

Between Planned Parenthood Great Plains ("PPGP") and Dr. Orrin Moore, M.D.

This Memorandum of Understanding (MOU) sets forth the terms and understanding between PPGP and Dr. Moore to establish a plan for back-up care for medication abortion patients at the Patty Brous health center in Kansas City, as required for compliance with the Missouri Code of State Regulations.[1]

Purpose

To fulfill the requirements of 19 C.S.R. 10-15.050 and 19 C.S.R. 30-30.061, Dr. Moore agrees to serve as the 24/7 back-up physician to treat complications of medication abortion patients at the Patty Brous health center, including surgical follow-up. Dr. Moore will provide 24/7 back-up care except when it is determined that it is not in the patient's best interest or would not be in accordance with the standard of care.

Dr. Moore states that he is a board-certified OB/GYN who has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

Duration

This MOU shall become effective upon signature by the individuals named herein and will remain in effect until modified or terminated by either party or by mutual consent. The parties understand that, should they desire to alter this MOU, they will notify the Missouri Department of Health and Human Services.

Date: 10/25/2017

Aaron Samulcek
Interim President & CEO, Planned Parenthood Great Plains

Date: 10/25/2017

Dr. Orrin Moore, M.D.
Medical Director, Planned Parenthood Great Plains

Americans United for Life

[1] At the time of signing, the regulations at issue were proposed emergency rules (19 C.S.R. 10-15.050 and 10 C.S.R. 30-30.061). This agreement will remain in force if and when those rules become effective.

ABMS® Board Certification Credentials Profile

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To become Board Certified, a physician must achieve expertise in a medical specialty or subspecialty that meets the profession-driven standards and requirements of one (or more) of the 24 ABMS certifying boards. To maintain Board Certification, the certifying boards may require physicians, depending on their date of initial certification, to participate in on-going programs of continuing learning and assessment (Maintenance of Certification) designed to help them remain current in an increasingly complex practice environment.

Orrin A. Moore (ABMSUID - 3712) Viewed:5/9/2017 10:34:43 PM CST

DOB: 12/01/1942

Education: 1976 MD (Doctor of Medicine)

Address: 38 E 30th St
New York, NY 10016-7374 (United States)

Individual NPI [1]: 1053441659

Show Active Medical License(s) [2]:

Certification:

ABOG American Board of Obstetrics & Gynecology

Obstetrics & Gynecology - General ***Status: Certified***

Status	Duration	Occurrence	Start Date - End Date	Participating in MOC
Active	Lifetime	Initial Certification	11/05/1982 -	Not Required

Learn more about Obstetrics & Gynecology MOC program

[1] NPI: Not for Primary Source Verification (PSV).

[2] State of Licensure provided by Federation of State Medical Boards (FSMB): Not for Primary Source Verification (PSV).

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Ronald Norman Yeomans (ABMSUID - 424462) Viewed:8/17/2017 10:37:08 PM CST

DOB: 12/08/1940

Education: 1967 MD (Doctor of Medicine)

Address: Comp Hlth Women
4401 W 109th St
Overland Park, KS 66211-1303 (United States)

Individual NPI [1]: 1417018557

Show Active Medical License(s) [2]:

Certification:

ABOG American Board of Obstetrics & Gynecology

Obstetrics & Gynecology - General ***Status: Certified***

Status	Duration	Occurrence	Start Date - End Date	Participating in MOC
Active	Lifetime	Initial Certification	1975 -	Not Required

Learn more about Obstetrics & Gynecology MOC program

[1] NPI: Not for Primary Source Verification (PSV).

[2] State of Licensure provided by Federation of State Medical Boards (FSMB): Not for Primary Source Verification (PSV).

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Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

July 18, 2018

Amanda Addison, VP of Operations (via e-mail: Amanda.addison@ppgreatplains.org)
Planned Parenthood Great Plains
1001 Emanuel Cleaver II Blvd
Kansas City, MO 64110

Regarding: Midtown Health Center-Patty Brous Center Inspection results (FID: #A005)

Dear Ms. Addison:

Your facility currently has an Abortion Facility license that expires August 10, 2018. 19 CSR 30-30.050(2)(I) states "No license shall be issued or renewed by the department until the department has inspected the facility and determined that it is in compliance with all requirements of applicable regulations and statutes."

Representatives of the department conducted an inspection of the facility ending June 21, 2018. During the inspection it was determined that the facility has not performed any abortion procedures since March 29, 2018. There is not currently an approved physician available to perform abortions at the facility, nor any immediate plans to have one in place prior to the expiration of the license.

As a result of this lack of a physician, and as the facility is not currently capable of performing abortion procedures in compliance with all applicable statutory and regulatory requirements, a complete inspection could not be conducted.

Unless the facility can actively demonstrate compliance with all rules, and is again actively performing abortion procedures prior to the upcoming license expiration date, the Abortion Facility license cannot be renewed. Please inform the department as soon as possible prior to the expiration date if a new physician is acquired, a newly approved complication plan is in place, and when the facility can fully demonstrative compliance.

Note: If the current license expires, you may re-apply for a new license in the future when the facility is again able to demonstrate compliance with all applicable statutes and rules.

In addition to the issues related to lack of a physician, attached is a list of other findings (Statement of Deficiencies) that must be addressed and verified in compliance prior to a license renewal. Please respond in writing within ten (10) calendar days from receipt using the attached Plan of Correction (POC) template.

If you have additional questions do not hesitate to contact our office at BAC@health.mo.gov or via phone at 573-751-6083.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care

Americans United for Life

MO Bureau of Ambulatory Care—Facility Plan of Correction (POC) Form

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Midtown Health Center (a/k/a Patty Brous Health Center)	Survey Exit Date (from CMS 2567)	June 21, 2018
Facility Address/ City/Zip	1001 Emanuel Cleaver II Blvd, Kansas City, MO 64110	State or Federal SOD Q-tags, L-tags, K-tags, E-tags	L000, L1072, L1076, L1081, L1084, L1090, L1101, L1104, L1109, L1113, L1118, L1120, L1122, and L1194

1. Include a copy of the first page of *each* of the original forms CMS-2567 Statement(s) of Deficiencies for Federal (Q-tags), State (L-tags), Life Safety (K-tags) and Emergency Preparedness (E tags) ***signed & dated by administrator*** or designee, along with associated completed POC forms no later than ten (10) calendar days from receipt. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-6083. Our fax number is 573-751-6158.

2. Complete a **separate POC form for each applicable regulation set of the Statement of Deficiencies** (federal Q tags, state L tags, Life Safety K tags and Emergency Preparedness E tags).

3. Required elements of an acceptable Plan of Correction. Chapter 2 of the State Operations Manual (2728B) describes necessary elements for an acceptable POC. **Each** deficiency shall be addressed separately by completing the applicable information for **each** element below for **every** citation for Q-tags, L-tags, K-tags and E tags.

   A: Indicate the prefix or Tag number for each citation indicated on the form CMS-2567 "Statement of Deficiencies" (Q001, L125, etc)

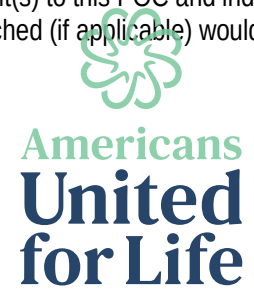
   B: Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete.

   C: For each deficiency, indicate date correction will be made or all components for correction put in place. Can NOT be prior to the Exit Date, and generally must be no later than 60 days from receipt of the CMS-2567, per 42 CFR 488.28. *(Limited extensions may be granted upon written request should extraordinary circumstances exist.)* To maximize correction opportunities, correction should be less than 45 days from Exit. Note: the monitoring required in "E" below will generally extend past this date.

   D: For each deficiency, include the Title of the person responsible for implementing the plan of correction for each deficiency.

   E: Describe the monitoring and/or tracking procedure that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. If the person responsible for ongoing monitoring is different than the person named in "D," note it here.

   F: Evidence/Exhibit attachment(s). Each POC form should stand on its own, and Element B should fully explain the actions the facility has taken or will take. Although not formally part of the POC, if written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A". Examples of routine exhibits expected to be attached (if applicable) would be:
   F1: Copies of applicable portions of any revised/amended facility policy to address the deficiency.
   F2: In-service/staff training attendance sheets.
   F3: Work orders or equipment service reports.
   F4: Meeting minutes or QA monitoring tools.



A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L000	As L000 includes only background information and initial comments, CHPPGP offers no plan of correction.	N/A	N/A	N/A	N/A

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1072	CHPPGP objects to the deficiency identified in L1072 as it appears to require that the administrator of an abortion facility must be present even when the building is being operated as a family planning clinic by a different entity, Planned Parenthood Great Plains ("PPGP"). PPGP is not licensed to and does not operate an abortion facility; therefore, it cannot be required to have on-site an administrator of an abortion facility. CHPPGP offers the following response to each finding contained within L1072: 1. As stated on the designation of the acting administrator form produced to DHSS, the designation applies to CHPPGP, not PPGP. 2. When DHSS arrived for its inspection, PPGP was operating the facility as a family planning clinic. No abortions were being provided or, as DHSS notes, had been provided for a period of months. The then-administrator of CHPPGP's Kansas City abortion facility, along with the designated acting administrator for times when the administrator was unavailable, went to the facility to make themselves available to inspectors, even though CHPPGP was not in operation on that date. 3. DHSS cites no regulation that requires a non-abortion facility to abide by abortion facility requirements.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

Americans United for Life

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	CHPPGP notes that it has selected a new administrator for its abortion facility, and it will ensure that employee – or the employee designated to act as administrator in her absence – will be on-site for any dates on which CHPPGP operates the Kansas City facility.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1076	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. For clarification of DHSS's findings, CHPPGP notes that at no time did it offer abortion care without a qualified provider.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1081	CHPPGP will conduct future drills to include both part-time ("PRN") employees and temporary contractors, if applicable, to ensure that all employees who may be on-site when CHPPGP is operating the Kansas City facility are prepared for evacuation during a disaster. CHPPGP will conduct two additional drills in the next 45 days to ensure all employees participate.	Two drills will be conducted by 9/13/18. CHPPGP employees at the KC facility will participate in at least one of those drills.	Facility Administrator	Administrator will review the current written plan for evacuation of patients and personnel in the event of a fire, explosion, active shooter or other disaster with VP of Health Services. She will then conduct two evacuation drills prior to September 13, 2018. All CHPPGP employees of the KC facility will participate in at least one of those drills.	N/A

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP will take the following steps in response to the items identified in this finding: 1. **Arrange an in-person meeting with its environmental services cleaning provider to review its expectations and standards**. Facility Administrator, Regional Director of Health Center Operations, and Vice President of Operations, will attend the meeting and review with the environmental services provider each of the areas identified in DHSS's report. This step is designed to address the dust-related portions of the finding. 2. **Document on a log the daily inspection performed by personnel at the KC facility prior to seeing patients.** The log will be maintained for 30 days by Administrator and submitted to Regional Director for review. This step is designed to address the dust-related portions of the finding. 3. **Administrator and VP of Operations will review with CHPPGP's facilities coordinator the following issues**: 1) chipped or peeling laminate and the sink in Observation 5; the cabinet doors with labels and/or adhesive tabs in Observation 6; and the cabinet under the sink, the cabinet under the sterilizer and the upper cabinets with labels and/or adhesive in Observation 7. The	Item 1 will occur within 30 days of the submission of this POC. Item 2 will commence on 8/15/18, be evaluated daily, and conclude on 9/14/18. The meeting outlined in Item 3 will be concluded by 8/20/18, and repairs/replacements will be	Vice President of Operations	Item 1, a one-time meeting, will be monitored by Facility Administrator and Regional Director. Item 2 will be monitored on a daily basis by Facility Administrator and on a weekly basis by Regional Director. Item 3 will be monitored by VP of Operations. In addition to scheduling the initial meeting prior to 8/20/18, VP of Operations will oversee repairs and/or replacements, as necessary.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	facilities coordinator will outline a process for repair and/or replacement for those items. 4. The disposable pad identified in Observation 5 has been removed, and instruments will be placed directly on the cart in the future. CHPPGP seeks to clarify that, to the extent any employee interviewed by DHSS surveyors described the cessation of abortion services on a date different than reflected in electronic health records, such errors were caused only by employees' attempts to recall specific dates that were months prior to the unannounced inspection. CHPPGP made no attempt to prevent disclosure of dates on which abortions were performed and permitted DHSS to review requested records from any and all dates on which abortions were provided. Additionally, CHPPGP completes intentional termination of pregnancy (ITOP) reports on a monthly basis and provides those reports to DHSS. The KC facility's ITOP reports reflect that the most recent procedures were performed on March 29, 2018. CHPPGP notes that, as part of the items reviewed for the L1084 finding, the surveyor cited to Recommendation II.a of AORN's "Guideline for Environmental Cleaning." One portion of that guideline specifically described procedures for a "surgical environment" in which "an operative or invasive procedure" was being conducted. As DHSS is aware, CHPPGP does not perform any surgical	concluded by September 14, 2018.			

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	procedures at its Kansas City facility and is licensed to provide medication abortion procedures.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1090	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. For clarification of DHSS's findings, CHPPGP notes that at no time did it offer abortion care without a qualified provider. Additionally, CHPPGP notes that, at all times during which it operated in 2017-2018, at least one licensed employee with current CPR training was onsite. Specifically, a DHSS surveyor reviewed the personnel file for the physician who provided abortion care at the Kansas City facility in 2017 and 2018. That file reflected that the provider had current CPR certification.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1101	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. CHPPGP is unable to provide additional responsive information, as this finding did not identify any specific instances in which CHPPGP was *not* in compliance; instead, it stated only that it could not be evaluated.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1104	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. CHPPGP notes that, although personnel reported that no ultrasound machine was at the facility on the date of the inspection, its machine will be returned to the Kansas City facility prior to resuming abortion services. DHSS did not identify any abortions provided since the Kansas City facility received its license in 2017 that lacked ultrasound images in patients' electronic health records. CHPPGP is unable to provide additional responsive information, as this finding did not identify any specific instances in which CHPPGP was *not* in compliance; instead, it stated only that it could not be evaluated. Additionally, as noted by DHSS in its findings, CHPPGP did not provide abortion services during the period in which the certification/training requirement for ultrasound-performing personnel was in effect.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1109	CHPPGP objects to the deficiency identified in L1109 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that each patient receiving abortion care is provided with discharge instructions that include the following hand-outs: 1) How to Take the Pills for Your Abortion and What to Expect; and 2) Taking Your Abortion Pills (with specific information for each patient). DHSS's report does not state, however, that an entry is made by CHPPGP personnel in each patient's medical record that the patient received copies of those documents. That entry satisfies the regulation's requirement that written discharge instructions be provided to patients.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1113	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. CHPPGP is unable to provide additional responsive information, as this finding did not identify any specific instances in which CHPPGP was *not* in compliance; instead, it stated only that it could not be evaluated.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1118	CHPPGP objects to the deficiency identified in L1118, as DHSS's interpretation of the regulatory language appears to contradict the plain language (and intent) of state law. The daily roster produced by CHPPGP to the surveyors included patients in the following three categories: 1) patients meeting with CHPPGP personnel for state-mandated consent visits to begin the 72-hour waiting period; 2) patients scheduled to have an abortion procedure; and 3) patients returning to the facility for a follow-up visit after having an abortion procedure. CHPPGP interprets the term "abortion services," as used in 19 CSR 30-30.060(3)(A) to include *all patients* in those three categories, as DHSS and the State of Missouri regulate elements of each of those visits. If DHSS wishes to change its interpretation of the regulation (and state law) such that neither the mandated consent visit nor follow-up care is included in the regulation's description of "abortion services," CHPPGP will produce a different roster. To the extent DHSS intends to continue imposing regulations that relate to both the mandated consent visit and follow-up care to an abortion procedure, CHPPGP will maintain a daily roster with all three types of visits. CHPPGP is willing to work to identify an alternative way of pulling a daily roster from its electronic health	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	records that reflects only patients scheduled for an abortion procedure on a given day; however, that process is intended only for the convenience of surveyors and not for compliance with 19 CSR 30-30.060(A), for the reasons outlined above.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1120	CHPPGP objects to the deficiency identified in L1120 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that the physician providing care signed and dated the visit summary generated by the electronic health record, which reflects the medications prescribed during the patient encounter. To CHPPGP's knowledge, DHSS has never previously interpreted this regulation to require *each separate portion* of a patient's medical record be signed and authenticated by the treating physician. CHPPGP will, however, seek to alter the layout of its electronic health record to create an additional place for the physician to sign, date, and time medication orders for each patient. This entry will be duplicative of that information on the patient's visit summary.	CHPPGP will work with the software provider for its electronic health records system to implement this change by September 14, 2018.	Vice President of Operations	VP of operations will work with the software provider to ensure the electronic records template is changed by September 14, 2018. Facility Administrator will review electronic health records for all patients receiving abortion care for one month after the revised template becomes effective to monitor for compliance.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1122	CHPPGP objects to the deficiency identified in L1122 to the extent it misstates the nature of the information conveyed during the survey process. For each of the patient records reviewed by the surveyor, a physician or qualified health professional (as defined by § 188.027, RSMo) provided the state-mandated information to patients receiving abortion care. The records described in L1122 reflected that persons meeting the statutory and regulatory definitions gave the required information. DHSS's interpretation appears to be that CHPPGP is *prohibited* from providing any additional information, including education, to patients by trained personnel who do not meet the statutory definitions. Upon questioning a DHSS surveyor, CHPPGP staff were informed that the facility's current practice "complied with the law but not the regulation." That response provides no guidance to CHPPGP, and CHPPGP is unwilling to limit the factually accurate information it provides to patients, particularly when it provides the required information by personnel who meet the state's definitions. Personnel who do not meet the statutory or regulatory definitions of "qualified professional" are available to reiterate portions of the information also provided by physicians or "qualified professionals," outlining alternatives to abortion and reiterating that a physician is available to answer patient questions.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	It is CHPPGP's position that providing information from multiple sources is the most efficient, patient-centered approach possible, and it is committed to continuing that practice.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1194	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

January 30, 2019

Amanda Addison, R.N, BSN, MBA, VP of Operations
Comprehensive Health of Planned Parenthood Great Plains, Inc.
1001 Emanuel Cleaver II Blvd.
Kansas City, MO 64110

Dear Ms. Addison:

The Department conducted an annual licensure inspection of Comprehensive Health of Planned Parenthood Great Plains, Inc. in Kansas City on June 21, 2018. At that time, it was determined that your agency had not conducted an abortion since March 2018, due to lack of physician services. As a result, compliance with several legal and regulatory requirements could not be verified.

In August 2018, your agency received approval of a newly submitted complication plan, based on your acquisition of physician services provided by Dr. Coleen McNicholas. The Department conducted a revisit of your agency on September 19, 2018, and found that your agency was in compliance with legal requirements at that time (see attached Statement of Deficiencies).

During the September revisit to your agency, Dr. McNicholas informed Department staff that she was in the process of seeking privileges at Menorah Medical Center (Overland Park, KS), in accordance with the licensure requirements outlined in Chapter 188.027, 188.080, 197.215 and 19 CSR 30-30.060 (1)\(C)(4). She further stated that she expected the privileges to be granted no later than January 2019.

The purpose of this letter is to seek an update as to Dr. McNicholas' progress towards obtaining the required privileges. At your earliest convenience, please contact me at 573-751-1588 to discuss this matter.

Respectfully,

Melinda Laughlin, Chief
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired: 1-800-735-2466 VOICE: 1-866-735-2460

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 20, 2018

Brie Anderson
Vice President for Health Services
Comprehensive Health of Planned Parenthood Great Plains, Inc.
4401 W. 109th Street, Suite 200
Overland Park, Kansas 66211

Via email to: Brie Anderson@ppgreatplains.org

RE: Complication plan submitted for Comprehensive Health of Planned Parenthood Great Plains, Inc., located at 1001 Emanuel Cleaver II Blvd., Kansas City, MO 64110

Ms. Anderson:

This letter serves as written approval of the proposed complication plan, submitted to the DHSS on July 26, 2018, for the above referenced facility.

Please be advised that the facility license (17-2) expired on August 10, 2018, and no abortions may be performed until such time as DHSS verifies compliance with the provisions of applicable abortion laws through an onsite inspection. A representative of the DHSS will contact you in order to schedule an initial inspection.

Sincerely,

William Koebel
Section Administrator
Section for Health Standards and Licensure

cc: vicki.casey@ppgreatplains.org

Americans United for Life

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, INC.

Department of Health and Senior Services Complication Plan

DIVISION:	Health Services	**EFFECTIVE DATE:**	July 26, 2018
WORK PRACTICE:	DHSS Medical Abortion Complication Plan	**NUMBER OF PAGES:**	3
DOCUMENT RELATED TO:	§ 188.021, RSMo, and 19 CSR 30-30.061		
FACILITY LOCATION:	Comprehensive Health of Planned Parenthood Great Plains, Inc. (CHPPGP) – Kansas City facility		

I. Purpose

This plan is submitted in order to comply with § 188.021, RSMo, and 19 CSR 30-30.061, which require that facilities licensed to perform abortions must have in place a complication plan that meets certain standards.

II. Facility Physicians

This plan applies to CHPPGP's licensed abortion facility in Kansas City (the Patty Brous facility). The physician performing medication abortions in Kansas City (Dr. Colleen McNicholas, D.O.) is board-certified by the American Board of Obstetrics and Gynecology. In addition to this physician, CHPPGP's Medical Director (Dr. Orrin Moore, M.D.) is board-certified by the American Board of Obstetrics and Gynecology. Dr. Moore has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center. Whenever possible, Dr. McNicholas will personally treat complications experienced by her medication abortion patients. When Dr. McNicholas is unavailable to treat complications, Dr. Moore shall personally treat complications 24/7 relating to medication abortions, including by providing surgical follow-up care. If Dr. Moore is ever unavailable to treat complications, Dr. Ronald Yeomans, M.D., who is also board-certified by the American Board of Obstetrics and Gynecology, shall personally treat complications 24/7 during Dr. Moore's period of unavailability. Dr. Yeomans has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

III. Treatment of Complications

CHPPGP maintains an answering service for which a nurse (RN, LPN, or NP) is on call 24/7 to address patients' questions and concerns. A board-certified OB/GYN physician is available to the on-call nurse 24/7 to respond to questions and determine plan of care, if necessary.

Patients who have a medication abortion must receive written post-abortion care instructions that:

- provide signs and symptoms of problems to watch for;
- instruct patients on what to do if a problem occurs, including when to contact the on-call nurse; and
- provide the phone number of the answering service to reach the on-call nurse.

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, INC.

Department of Health and Senior Services Complication Plan

When a patient calls the 24/7 answering service, the call will be forwarded to the on-call nurse. The on-call nurse must be trained to assess each patient individually and identify and manage problems the patient may be experiencing, in accordance with established protocols.

After the patient is personally assessed, and if the on-call nurse and/or the on-call OB/GYN physician determines that follow-up care is needed, the patient will be directed to return to a health center to receive such care. If a patient requires follow-up care from a physician, Dr. McNicholas, Dr. Moore, or Dr. Yeomans will personally treat complications relating to medication abortions, including those requiring surgical intervention, which were provided to patients at the Patty Brous facility.

However, if after the patient is personally assessed and if the on-call nurse and/or Dr. McNicholas, Dr. Moore, or Dr. Yeomans determines that it is not in the patient's best interest or it would not be in accordance with the standard of care for the patient to receive follow-up treatment from Dr. McNicholas, Dr. Moore, or Dr. Yeomans, the patient will be instructed to go to her nearest emergency room. The patient must be instructed to take with her to the emergency room the written take-home instructions that were previously provided to her, which explain that the patient received abortion care, and encourages the emergency room to contact the 24/7 answering service. The patient must also be instructed to call the on-call nurse once she arrives at the emergency room.

The on-call nurse must not, as a matter of course, call the emergency room in advance without the patient's consent in order to protect her confidentiality and privacy, as the patient may decide to go to a different hospital for a variety of reasons (such as financial issues, insurance coverage, or concerns about confidentiality).

Once the patient arrives at the emergency room, she or, with the permission of the patient, the attending physician or other clinician managing her care should call the CHPPGP on-call nurse so that the attending physician or other clinician managing the patient's care can be briefed on the care the patient received.

On-call nurses document each call, including those that do not involve complications, and enter notes into patient records. The on-call nurses maintain communication with each other regarding patients who were assessed and require follow-up care.

IV. Follow-up Care

In the event the on-call nurse advises a patient to seek emergency care, a follow-up call is made by CHPPGP to that patient within 24 hours. The follow-up call is to be documented in NextGen.

V. Reporting

The OB/GYN treating a patient's complication shall prepare a complication report as required by § 188.052, RSMo, and ensure that the report is submitted to the Missouri Department of Health and Senior Services and placed in the patient's medical record.

VI. Covered Physicians

The CHPPGP physician covered by this plan is Dr. Colleen McNicholas, D.O. The OB/GYN providing 24/7 back-up complication coverage is Dr. Orrin Moore, M.D. Dr. Ronald Yeomans, M.D., has agreed to provide 24/7 back-up complication coverage in any instance in which Dr. Moore is unavailable. A copy of the written agreement between CHPPGP and Drs. Moore and Yeomans is attached to this plan, along with a copy of the OB/GYN board certification credentials profiles for Drs. McNicholas, Moore, and Yeomans.

Memorandum of Understanding

Between Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP")
and Drs. Orrin Moore, M.D., and Ronald Yeomans, M.D.

This Memorandum of Understanding (MOU) sets forth the terms and understanding between CHPPGP and Drs. Moore and Yeomans to establish a plan for back-up care for medication abortion patients at the Patty Brous health center in Kansas City, as required for compliance with the Missouri Code of State Regulations.

Purpose
To fulfill the requirements of 19 C.S.R. 10-15.050 and 19 C.S.R. 30-30.061, Dr. Moore agrees to serve as the 24/7 back-up physician to treat complications of medication abortion patients at the Patty Brous health center, including surgical follow-up. Dr. Moore will provide 24/7 back-up care when Dr. McNicholas is unavailable to treat complications for Patty Brous patients, except when it is determined that it is not in the patient's best interest or would not be in accordance with the standard of care.

Dr. Moore states that he is a board-certified OB/GYN who has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

At those times when Dr. Moore is unavailable to provide 24/7 back-up care, Dr. Ronald Yeomans agrees to serve as the 24/7 back-up physician to treat complications of medication abortion patients at the Patty Brous health center, including surgical follow-up. Dr. Yeomans will provide 24/7 back-up care when Dr. Moore is unavailable, except when it is determined that it is not in the patient's best interest or would not be in accordance with the standard of care.

Dr. Yeomans states that he is a board-certified OB/GYN who has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

Duration
This MOU shall become effective upon signature by the individuals named herein and will remain in effect until modified or terminated by either party or by mutual consent. The parties understand that, should they desire to alter this MOU, they will notify the Missouri Department of Health and Human Services.

Amanda Addison Date: 7/26/18
Amanda Addison
Vice President of Operations, Comprehensive Health of Planned Parenthood Great Plains, Inc.

Date: 7/26/2018
Dr. Orrin Moore, M.D.
Medical Director, Planned Parenthood Great Plains

Ronald W Yeomans, MD Date: 7/26/18
Dr. Ronald Yeomans, M.D.
Contract Physician, Planned Parenthood Great Plains

Americans United for Life

ABOG

American Board of Obstetrics + Gynecology

First in Women's Health

July 24, 2018

RE: Certification Status of Colleen P. McNicholas, D.O.

To Whom It May Concern:

Colleen P. McNicholas, D.O. is a Diplomate of the American Board of Obstetrics & Gynecology (ABOG).

Obstetrics and Gynecology Certification

ABOG ID Number: 9025020
Original Certification Date: 1/17/2014
Certification Status: Valid through: 12/31/2018
Participating in Maintenance of Certification: Yes

A physician becomes a Diplomate of the ABOG when he/she has fulfilled all requirements, has satisfactorily completed the written and oral examinations and has been awarded ABOG's certifying diploma.

Physicians certified by the ABOG in Basic Obstetrics and Gynecology prior to 1986 or subspecialty certified prior to November, 1987 hold non-time-limited (non-expiring) certificates. They are not required to participate in Maintenance of Certification.

Sincerely,

George D. Wendel, Jr. M.D.
Executive Director

Americans United for Life

2915 Vine Street, Dallas, Texas 75204 | P: 214.871.1619 | F: 214.871.1943 | E: info@abog.org | W: ABOG.org

A265980

ABOG

American Board of Obstetrics + Gynecology

First in Women's Health

July 24, 2018

RE: Certification Status of Orrin A. Moore, M.D.

To Whom It May Concern:

Orrin A. Moore, M.D. is a Diplomate of the American Board of Obstetrics & Gynecology (ABOG).

Obstetrics and Gynecology Certification

ABOG ID Number: 19102
Original Certification Date: 11/1/1982
Certification Status: Non-Expiring
Participating in Maintenance of Certification: Not required at this time

A physician becomes a Diplomate of the ABOG when he/she has fulfilled all requirements, has satisfactorily completed the written and oral examinations and has been awarded ABOG's certifying diploma.

Physicians certified by the ABOG in Basic Obstetrics and Gynecology prior to 1986 or subspecialty certified prior to November, 1987 hold non-time-limited (non-expiring) certificates. They are not required to participate in Maintenance of Certification.

Sincerely,

George D. Wendel, Jr. M.D.
Executive Director

Americans United for Life

2915 Vine Street, Dallas, Texas 75204 | P: 214.871.1619 | F: 214.871.1943 | E: Info@abog.org | W: ABOG.org

A139998

ABOG

American Board of Obstetrics + Gynecology

First in Women's Health

July 24, 2018

RE: Certification Status of Ronald N. Yeomans, M.D.

To Whom It May Concern:

Ronald N. Yeomans, M.D. is a Diplomate of the American Board of Obstetrics & Gynecology (ABOG).

Obstetrics and Gynecology Certification

ABOG ID Number: 7329
Original Certification Date: 1/1/1975
Certification Status: Non-Expiring
Participating in Maintenance of Certification: Not required at this time

A physician becomes a Diplomate of the ABOG when he/she has fulfilled all requirements, has satisfactorily completed the written and oral examinations and has been awarded ABOG's certifying diploma.

Physicians certified by the ABOG in Basic Obstetrics and Gynecology prior to 1986 or subspecialty certified prior to November, 1987 hold non-time-limited (non-expiring) certificates. They are not required to participate in Maintenance of Certification.

Sincerely,

George D. Wendel, Jr. M.D.
Executive Director

Americans United for Life

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A017121

Release and Settlement Agreement

This Release and Settlement Agreement is made and executed by and between Planned Parenthood of Kansas and Mid-Missouri, Inc., (hereinafter referred to as "PPKM"), the Missouri Department of Health and Senior Services, (hereinafter referred to as "DHSS"), Margaret Donnelly, in her official capacity as the Director of DHSS (hereinafter referred to as "Donnelly"), Chris Koster, in his official capacity as Attorney General of the State of Missouri (hereinafter referred to as "Koster"), James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, Missouri (hereinafter referred to as "Kanatzar"), and Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, Missouri (hereinafter referred to as "Knight"), (DHSS, Donnelly, Koster, Kanatzar, and Knight will hereinafter be referred to collectively as "Defendants"; PPKM and Defendants will hereinafter be referred to collectively as the "Parties.") The Parties enter into this agreement through their respective lawyers.

For due and good consideration recited herein, the Parties agree and state as follows:

1. **Plaintiff.** PPKM is the Plaintiff in lawsuits styled (1) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Jane Drummond, et al.*, No. 07-4164-CV-C-ODS, in the United States District Court for the Western District of Missouri, Central Division; (2) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00463, filed in the Cole County Circuit Court; and (3) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00276, filed in the Cole County Circuit Court.

(These lawsuits will hereinafter be referred to collectively as the "Lawsuits.")

2. **Defendants.** Defendants are named as the defendants in the Lawsuits.

3. **Scope of Agreement.** This Agreement embodies the entire agreement and understanding of the Parties with respect to the subject matter contained herein. The Parties hereby declare and represent that no promise, inducement, or agreement not herein expressed has been made, and the Parties acknowledge that the terms and conditions of this Agreement are contractual and not a mere recital.

4. **Non-Admission.** No actions taken by the Parties, or any of them, either previously or in connection with this Agreement shall be deemed or construed to be an admission of the truth or falsity of any matter pertaining to any claim or defense alleged in the pleadings filed on behalf of the Parties in the Lawsuits, or an acknowledgment by any of the Parties of any liability to the other parties or to any person for any other claim, demand, or action, all liability being expressly denied by the Parties.

5. **Consideration.** In consideration for (1) PPKM's dismissal of the Lawsuits; (2) PPKM's release of claims as set forth in paragraph 10 of this Agreement; (3) PPKM's agreement to complete structural changes at the Columbia Center and to otherwise comply with 19 CSR 30-30.070(2), as set out in paragraph 6 of this Agreement; and (4) PPKM's agreement that the Brous Center will comply with certain provisions of 19 CSR 30-30.050 and 19 CSR 30-30.060, as set out in paragraph 7 of this Agreement, the Defendants agree that DHSS will approve the Columbia Center and the Brous Center for licensure as abortion facilities.

6. **Modifications of the Columbia Center.** PPKM agrees to make modifications to its facility located in Columbia, Missouri ("Columbia Center") as set out in the attached Addendum A. PPKM anticipates being able to begin construction within nine months of the date that this Agreement is finally signed by all the parties and completing construction within sixteen months from the date this Agreement is finally signed by all the parties, and agrees that while certain factors relevant to this timing (such as the DHSS's approval of its architectural drawings and sprinkler plans) are not under PPKM's control, it will make a good-faith effort to comply with these time frames.

PPKM agrees that it will submit architectural drawings showing the modifications to be made, as set out in Addendum A, to DHSS before work begins at the Columbia Center, including the agreed upon modifications in the sterilization and soiled rooms, and the sprinkler plans. PPKM agrees that DHSS shall be granted entry onto the Columbia Center premises for a mid-construction progress inspection. DHSS agrees that it will give PPKM at least 7 days prior notice of the proposed date for its progress inspection, which shall commence at an agreed upon date and time convenient to both parties. DHSS will be available for follow up questions and approval of specific construction or design questions as they arise and will endeavor to provide prompt responses to the Columbia Center during the construction and pre-approval phases.

PPKM agrees to permit DHSS to conduct a final inspection of the Columbia Center within 2 weeks of the completion of the structural modifications set out in Addendum A and before an abortion facility license is issued to ensure that the modifications at the Columbia

Center have been completed as agreed and also to ensure that the Columbia Center is also in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A. If this inspection reveals that the modification set out in Addendum A have not been completed as agreed, or that the Columbia Center is not in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, PPKM agrees that it will make a good-faith effort to complete the remaining work needed for the Columbia Center to complete the modifications set out in Addendum A, and to be in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, within six weeks.

DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the requirements of 19 CSR 30-30.070(2) except as specifically set forth in Addendum A, and will not require changes not set forth in Addendum A unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to no longer be in compliance with those requirements.

7. **Brous Center.** PPKM will comply with the procedural, operational, and management requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, at its Brous Center location. Modifications to certain requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060 that will apply to the Brous Center are set forth in Addendum B.

PPKM agrees to permit an inspection of the Brous Center before an abortion facility license is issued to ensure that the Brous Center is in compliance with the requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, as modified by Addendum B.

The Parties acknowledge that the Brous Center currently does not perform surgical abortions. If the Brous Center at a future time wishes to provide surgical abortion services, PPKM will notify Defendants' counsel. PPKM understands that the performance of surgical abortions at the Brous Center would constitute a material change that would require the Brous Center to comply with additional regulations.

8. **Provision of Services.** It is the intention of the Parties and Defendants that the Columbia Center may continue providing abortion services throughout the process of preparing for and completing the modifications described in paragraph 6, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process. It is the intention of the Parties and Defendants that the Brous Center may continue providing medication abortion services during the abortion facility license application process, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process.

9. **Dismissal of the Lawsuits.** Upon payment of the fees and expenses set forth in Paragraph 12 of this Agreement, the Parties shall also execute the following Stipulations of Prejudicial Dismissal: (a) a Stipulation of Prejudicial Dismissal pursuant to Fed. R. Civ. P. 41(a)(1)(ii), to be filed the federal lawsuit identified in paragraph 1 of this Agreement, dismissing with prejudice PPKM's claims in their entirety; and (b) Stipulations of Prejudicial Dismissal pursuant to Mo. R. Civ. P. 67.02, to be filed in the state lawsuits identified in paragraph 1 of this Agreement dismissing with prejudice all claims raised in those lawsuits.

10. **Release.** PPKM does hereby release, acquit, and forever discharge the

Defendants, the State of Missouri, and any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, of all and from any and all liability, claims, actions, causes of action, demands, rights, damages, costs, interest, loss of service, expenses, and compensation whatsoever, whether or not now known or contemplated, which PPKM now has, or which may hereafter accrue, against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on or arising out of the allegations in the Lawsuits relating to the licensure of the Columbia and Brous Centers. PPKM specifically acknowledges that it is forever barred from filing suit against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on any claim based on or arising out of the allegations in the Lawsuits relating to licensure of the Columbia and Brous Centers.

11. **Full Consideration.** PPKM acknowledges that the consideration described in paragraph 5 of this Agreement is all that it or its representatives are ever to receive from the State of Missouri, the Defendants, or any person or entity related to them whatsoever, for the settlement described in this Agreement, whether in settlement of PPKM's claims for damages, attorney's fees, costs, or other claims which were or could have been asserted in the Lawsuits.

12. **Attorney's Fees, Costs and Expenses.** In exchange for payment of $80,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and the regulations implementing that law to the

Columbia Center, and payment of $65,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and regulations implementing that law to the Brous Center in the federal lawsuit, PPKM hereby waives any remaining claim it might have against the State of Missouri, the Defendants in the Lawsuits, or any current or former employee, agent, agency, actor, or contractor of the State for attorney's fees, expenses, or costs, pursuant to 42 U.S.C. § 1988, or any other statute, rule, or other provision of law which is or may be in any way applicable hereto. The payment of $145,000.00 will be issued to Plaintiff's counsel by June 30, 2010.

13. **Court Costs.** The Parties will bear their own court costs.

14. **Non-Assignment.** PPKM hereby represents, acknowledges, and warrants that it has not at any time heretofore assigned to any other person or entity all or any portion of any claim or potential claim whatsoever that it may have, or may have had, against the Defendants, the State of Missouri, or any person or entity whatsoever based on or arising out of the allegations contained in the Lawsuits.

15. **Binding Effect.** The persons signing this Agreement represent that they have read this Agreement and fully understand its provisions. The signatories of the Parties declare that they are of legal age and that they have relied solely upon their own judgment without influence of anyone in making this Agreement. This Agreement shall be binding upon, and inure to the benefit of the heirs, personal representatives, successors, and assigns of the Parties.

16. **Preparation of Documents.** This Agreement is the joint work product of the

Parties and, in the event of any ambiguity herein, no inference shall be drawn against a party by reason of document preparation.

17. **Further Execution.** Each party hereto shall execute any and all documents as are necessary or desirable to consummate the transactions contemplated hereby.

18. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be deemed executed as of the date the Agreement was finally signed by the Parties below.

PLANNED PARENTHOOD OF KANSAS
AND MID-MISSOURI, INC.

By: _____

Title: Attorney for PPKM

STATE OF New York)
) ss
COUNTY OF New York)

Before me, a notary public for the State of New York, personally appeared Jonn for Sandmann, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Planned Parenthood of Kansas and Mid-Missouri, Inc., and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18 day of May, 2010.

_____
Notary Public

My commission expires on 11/9/13.

DARA KLASSEL
NOTARY PUBLIC-STATE OF NEW YORK
No. 02KL4913955
Qualified In New York County
My Commission Expires 11/9/13

MISSOURI DEPARTMENT OF HEALTH
AND SENIOR SERVICES

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF Missouri)
) ss
COUNTY OF Cole)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for the Missouri Department of Health and Senior Services with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08500003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

MARGARET DONNELLY, in her official capacity as Director, Missouri Department of Health and Senior Services

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Margaret Donnelly with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Margaret Donnelly, in her official capacity as Director of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08500003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012

CHRIS KOSTER, in his official capacity as Attorney General of Missouri

By: Emily A. Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Chris Koster with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Chris Koster, in his official capacity as Attorney General of Missouri, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number 08451008

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

JAMES KANATZAR, in his official capacity as Prosecuting Attorney of Jackson County

By: _____

Title: Prosecuting Attorney

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared James F. Kanatzar, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 26 day of May, 2010.

_____
Notary Public

My commission expires on _____.

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

MICHAEL A. WELLS
My Commission Expires
September 24, 2012
Jackson County
Commission #08499225

DANIEL KNIGHT, in his official capacity as Prosecuting Attorney of Boone County

By: Charles J. Dykhouse

Title: County Counselor for Boone County

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Charles J. Dykhouse, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18th day of May, 2010.

DEBORAH A. SPRAGUE
Notary Public - Notary Seal
State of Missouri
County of Boone
My Commission Expires August 10, 2012
Commission #08379045

Deborah A. Sprague
Notary Public

My commission expires on August 10, 2012.

ADDENDUM A

Work to Be Completed by Planned Parenthood of Kansas and Mid-Missouri at its Columbia Center as Described in Paragraph 6 of the Settlement Agreement

Corridors and Patient-Traveled Doors

In light of the Columbia Center's specific configuration, the Department determines that the facility's existing corridor width of 5 feet and door widths and construction are acceptable if combined with the following modifications. The door swing in the procedure and recovery rooms will be made so that they continue to swing into the room, but swing next to the wall and out of the way of the gurney. The fire extinguisher on the wall opposite the recovery room will be moved to the same side as the recovery room. The fire extinguisher adjacent to the procedure room will be moved to the same side as the procedure room. These modifications will provide extra maneuvering room for a stretcher into either room.

Construction Type/Sprinkler System

The Regulations require single story facilities to be Type II (111) construction. The facility will become fully equipped with a sprinkler system, which will be an acceptable alternative to the construction type. The design specifications for the sprinkler system must be submitted to the Department for approval before construction begins.

Dimensions for procedure room

The Regulations require the procedure room to be 12 feet length and width and a minimum ceiling height of 9 feet. The procedure room to be used by the Columbia Center is

12 feet by 9 feet, 1/2 inch, with a ceiling height of 8 feet, 6 inches. These dimensions are an acceptable alternative because the facility will only use one procedure room.

Personnel Change Rooms

The Regulations require personnel change rooms for each sex, be located convenient to the procedure room, and each equipped with a toilet and lavatory. The facility may have only one, unisex personnel change room because the facility will only use one procedure room.

Procedure Room Lighting

The Regulations require that the procedure room be equipped with a ceiling-mounted surgical light. The Department grants a deviation from this Regulation to the Columbia Facility provided that the procedure room be equipped with a wall-mounted surgical light and gooseneck light.

Patient Change Rooms

The Regulations require at least two patient change rooms with storage for personal effects. The facility shall be allowed to use only one patient change room and to have patient belongings travel with the patient in a secure container, if it uses only one procedure room and does not use the procedure room as the change room.

Counseling Room Dimensions

The Regulations require that counseling rooms shall be separate and not smaller than ten feet by ten feet (10' x 10'). The facility shall be allowed to use its counseling room that is eight feet by ten feet, eleven inches (8' x 10', 11'').

Scrub Facility

The Regulations require knee or foot-operated scrub facilities located immediately outside the procedure room. The Facility shall be allowed to use a hands-free scrub sink located in the former procedure room which will no longer be used as a procedure room, and which is adjacent to the usable procedure room.

Sterilizing Room

The Facility shall provide a sterilization room with positive air pressure in relation to adjacent areas, in accord with 19 CSR 30-30.070(2)(v). The Facility shall also provide a separate soiled/decontamination room with a constant running exhaust.

Additional Items:

The following items shall also be completed:

The facility shall install five (5) additional exit signs to clearly indicate the direction of exit travel.

The facility shall make ceiling tile in the clinical area so that it is smooth and easily cleanable.

The patient toilet facility shall be equipped with a constant running exhaust.

All open cabinet storage of supplies in the procedure room must be converted into closed cabinets in accord with the Regulations.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.070(2) shall apply in full to the Columbia Center. DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the

requirements of 19 CSR 30-30.070(2) except as specifically set forth above, and agrees that it will not require changes not set forth in above unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to be no longer in compliance with those requirements.

ADDENDUM B

Modifications of Brous Center requirements.

The Brous Center's quality assurance program will review all medication abortion complications, but will not be required to review the following items set forth in 19 CSR 30-30.060(3)(J) that are not applicable to medication abortion: cases that resulted in a stay of more than twelve (12) hours, and cases in which gestational age was determined to be beyond eighteen (18) weeks. The quality assurance program will not be required to review intraoperative and postoperative complications, however, complications of medication abortion, including incomplete or failed medication abortions that requires surgical completion, and hemorrhaging that requires surgical intervention following a medication abortion, shall be reviewed as part of the quality assurance program.

The Brous Center will not be required to provide medication abortion in a procedure room or a recovery room, and requirements that relate to the procedure and/or recovery room are therefore inapplicable. Continuous physician services or registered professional nursing services will be provided whenever an abortion patient is in the Brous Center, once the patient has received the mifepristone or other medication that begins the abortion process. PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060 (3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)(4). 19 CSR 30-30.060(3)(H)(2) and 19 CSR 30-

30.060(4) (A) through (C) do not apply to the inducement of medication abortions at the Brous Center.

The Brous Center will provide Anti-Rh immune globulin therapy to Rh negative patients during the appointment where the patient receives the mifepristone or other medication that begins the abortion process. The Brous Center need not perform urinalysis or a pelvic exam for every abortion patient, because it performs ultrasound on every patient to confirm pregnancy and gestational age. It will also perform hematocrit or hemoglobin and RH typing on every abortion patient. The option to perform a hemoglobin test instead of a hematocrit shall apply to the Columbia Center as well as the Brous Center.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.050 and 19 CSR 30-30.060 shall apply in full to the Brous Center.

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 18, 2016

Via email to abenson@bensonlaw.com

Arthur Benson
Arthur Benson & Associates
4006 Central Street
Kansas City, Missouri 64111-2236

Re: Comprehensive Health of Planned Parenthood Great Plains – Kansas City and Columbia facilities

Dear Mr. Benson:

This is in response to your November 11, 2016, letter to me regarding physician privileges at the Kansas City and Columbia, Missouri Planned Parenthood facilities.

Regarding physician privileges at the Kansas City facility, the 2010 settlement agreement states (page 19), "PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060(3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)4."

Your letter states that the Kansas City facility has a physician with surgical privileges at Overland Park Regional Medical Center who would provide medication abortions. Such privileges do not comply with the settlement agreement. Until the facility is in compliance with the privileges requirement of the settlement agreement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Regarding the Columbia facility, your letter states that the facility "has secured a written transfer agreement with a hospital within 15 minutes' travel time" from the facility "which fulfills 19 CSR 30-30.060(1)(C)(4)."[1] The department has not received a copy of this agreement and is therefore unable to confirm whether it complies with the regulation. Regardless, the facility still must comply with 19 CSR 30-30.060(1)(B)12, which states, "The administrator shall be responsible for ensuring that the provisions of Chapter 188 RSMo, Regulation of Abortions, are adhered to." Sections 188.027 and 188.080, RSMo,

[1] Regulation 19 CSR 30-30.060(1)(C)4 states, "Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility."

require that all physicians performing or inducing abortions have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced. Neither of the facility's two physicians have the required privileges. Until the facility is in compliance with the privileges requirement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Additionally, page two of your letter states, "A number of the remaining items you identified with respect to the Columbia facility seem far from a basis on which to deny licensing." To be clear, the department has not denied licensure; the department has identified the deficiencies that must be corrected before licensure could be granted.

If you have additional questions, you may contact our office at (573) 751-6083 or via email at the address below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

August 11, 2017

Amanda Addison (Amanda.addison@ppgreatplains.org)
Comprehensive Health of Planned Parenthood Great Plains
1001 Emanuel Cleaver II
Kansas City, MO 64110

Re: Comprehensive Health of Planned Parenthood Great Plains – Kansas City survey

Dear Ms. Addison:

The Department received the application for licensure of the Kansas City Planned Parenthood location (Brous Center) as an abortion facility. Department staff conducted an onsite survey of the facility on October 19, 2016 to determine compliance with the terms of the 2010 settlement agreement and applicable statutes and regulations. In a letter to the facility dated November 2, 2016, the Department identified the items that were not in compliance.

After the facility submitted a complete response and documentation regarding correction of the items that were not in compliance, the Department performed an onsite revisit of the facility on July 27, 2017. At the time of the revisit, the Department determined that the facility is in compliance with current legal requirements for licensure.

The abortion facility license is attached, effective date August 11, 2017.

If you have further questions, you may contact our office at 573-751-6083 or via email at the address noted below.

Sincerely,

John Langston

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A005	A. BUILDING: _____ B. WING _____	R 07/27/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	1001 EMANUEL CLEAVER II BLVD KANSAS CITY, MO 64110

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments On onsite, unannounced revisit survey was conducted on 07/27/2017 to follow up on items originally cited during the 10/19/16 inspection. The revisit was delayed due to ongoing legal action following the 10/19/16 inspection. Results of the 07/27/17 revisit indicate that the facility is now in compliance with applicable sections of 19 CSR 30-050 and 30.060 as well as the terms of the 2010 settlement agreement and applicable statutes.	{L 000}		

Hoffmann, Tracy

From: Langston, John
Sent: Wednesday, December 20, 2017 8:07 AM
To: Hoffmann, Tracy
Subject: FW: KC facility complication plan approval
Attachments: PPGP proposed complication plan updated 102717 - KC 4pm.pdf; PPGP - Brous complication plan attachments - 10.26.2017 updated.pdf

Print and then scan the email from Nikki as well as the attachments as one document to put on the O-drive as description "DHSS-approved complication plan for PPGP-Kansas City to comply with SB5. Approved 10/27/2017."

From: Loethen, Nikki
Sent: Friday, October 27, 2017 5:18 PM
To: Linneman, Dean; Creach, Julie; Koebel, William; Langston, John
Subject: FW: KC facility complication plan approval

From: Loethen, Nikki
Sent: Friday, October 27, 2017 4:57 PM
To: diana.salgado@ppfa.org
Subject: KC facility complication plan approval

Diana,
This email serves as the department's written approval for the attached complication plan (including attachments) for the KC facility.
Nikki

Nikki Loethen
General Counsel
Department of Health & Senior Services
912 Wildwood Drive
Jefferson City, MO 65102
Phone: 573.751.6005
Fax: 573.751.0247

From: Salgado, Diana [mailto:diana.salgado@ppfa.org]
Sent: Friday, October 27, 2017 3:59 PM
To: Loethen, Nikki
Subject: Re: FW: Comprehensive Health of PPGP's complication plan

Nikki -

We made the final edits you requested to the Kansas City ("Patty Brous") health facility's complication plan. Please confirm that the plan has been approved by the Department.

Thank you.

Diana O. Salgado
Senior Staff Attorney
Public Policy Litigation & Law
Planned Parenthood Federation of America
212-261-4399

Americans
United
for Life

PLANNED PARENTHOOD GREAT PLAINS – PATTY BROUS

Department of Health and Senior Services Complication Plan

DIVISION:	Health Services	**EFFECTIVE DATE:**	October 27, 2017
WORK PRACTICE:	DHSS Medical Abortion Complication Plan	**NUMBER OF PAGES:**	2
DOCUMENT RELATED TO:	Senate Bill 5		

I. Purpose

This plan is submitted in order to comply with Senate Bill 5 (HCS for SS for SB5, 99th General Assembly, Second Extraordinary Session (2017)). Pursuant to SB5, facilities licensed to perform abortions must have in place a complication plan that meets certain standards.

II. Facility Physicians

This plan applies to PPGP's licensed abortion facility in Kansas City (the Patty Brous facility). The physician performing medication abortions in Kansas City (Dr. Ronald Yeomans, M.D.) is board-certified by the American Board of Obstetrics and Gynecology. In addition to this physician, PPGP's Medical Director (Dr. Orrin Moore, M.D.) is a board-certified OB/GYN. Both of these OB/GYNs have admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center. As the Medical Director, Dr. Moore shall personally treat complications 24/7 relating to medication abortions, including by providing surgical follow-up care. If Dr. Moore is ever unavailable to treat complications, Dr. Yeomans will treat complications 24/7 during the time that Dr. Moore is unavailable.

III. Treatment of Complications

PPGP maintains an answering service for which a nurse (RN, LPN, or NP) is on call 24/7 to address patients' questions and concerns. A board-certified OB/GYN physician is available to the on-call nurse 24/7 to respond to questions and determine plan of care, if necessary.

Patients who have a medication abortion must receive written post-abortion care instructions that:

- provide signs and symptoms of problems to watch for;
- instruct patients on what to do if a problem occurs, including when to contact the on-call nurse; and
- provide the phone number of the answering service to reach the on-call nurse.

When a patient calls the 24/7 answering service, the call will be forwarded to the on-call nurse. The on-call nurse must be trained to assess each patient individually and identify and manage problems the patient may be experiencing, in accordance with established protocols.

After the patient is personally assessed, and if the on-call nurse and/or the on-call OB/GYN physician determines that follow-up care is needed, the patient will be directed to return to a health center to receive such care. If a patient requires follow-up care from a physician, Dr. Moore will

personally treat complications relating to medication abortions, including those requiring surgical follow-up care, which were provided to patients at the Patty Brous facility.

However, if after the patient is personally assessed and if the on-call nurse and/or Dr. Moore determines that it is not in the patient's best interest or it would not be in accordance with the standard of care for the patient to receive follow-up treatment from Dr. Moore, the patient will be instructed to go to her nearest emergency room. The patient must be instructed to take with her to the emergency room the written take-home instructions that were previously provided to her, which explain that the patient received abortion care, and encourages the emergency room to contact the 24/7 answering service. The patient must also be instructed to call the on-call nurse once she arrives at the emergency room.

The on-call nurse must not, as a matter of course, call the emergency room in advance without the patient's consent in order to protect her confidentiality and privacy, as the patient may decide to go to a different hospital for a variety of reasons (such as financial issues, insurance coverage, or concerns about confidentiality).

Once the patient arrives at the emergency room, she or, with the permission of the patient, the attending physician or other clinician managing her care should call the PPGP on-call nurse so that the attending physician or other clinician managing the patient's care can be briefed on the care the patient received.

On-call nurses document each call, including those that do not involve complications, and enter notes into patient records. The on-call nurses maintain communication with each other regarding patients who were assessed and require follow-up care.

IV. Follow-up Care

In the event the on-call nurse advises a patient to seek emergency care, a follow-up call is made by PPGP to that patient within 24 hours. The follow-up call is to be documented in NextGen.

V. Reporting

The OB/GYN treating a patient's complication shall prepare a complication report as required by § 188.052, RSMo, and ensure that the report is submitted to the Missouri Department of Health and Senior Services and placed in the patient's medical record.

VI. Covered Physicians

The PPGP physician covered by this plan is Dr. Ronald Yeomans, M.D. The OB/GYN providing 24/7 back-up complication coverage is Dr. Orrin Moore, M.D. A copy of the written agreement between PPGP and Dr. Moore is attached to this plan, along with a copy of Dr. Moore's and Dr.

Department of Health and Senior Services Complication Plan

Yeomans' OB/GYN board certification credentials profiles.

Memorandum of Understanding

Between Planned Parenthood Great Plains ("PPGP") and Dr. Orrin Moore, M.D.

This Memorandum of Understanding (MOU) sets forth the terms and understanding between PPGP and Dr. Moore to establish a plan for back-up care for medication abortion patients at the Patty Brous health center in Kansas City, as required for compliance with the Missouri Code of State Regulations.[1]

Purpose

To fulfill the requirements of 19 C.S.R. 10-15.050 and 19 C.S.R. 30-30.061, Dr. Moore agrees to serve as the 24/7 back-up physician to treat complications of medication abortion patients at the Patty Brous health center, including surgical follow-up. Dr. Moore will provide 24/7 back-up care except when it is determined that it is not in the patient's best interest or would not be in accordance with the standard of care.

Dr. Moore states that he is a board-certified OB/GYN who has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

Duration

This MOU shall become effective upon signature by the individuals named herein and will remain in effect until modified or terminated by either party or by mutual consent. The parties understand that, should they desire to alter this MOU, they will notify the Missouri Department of Health and Human Services.

Date: 10/25/2017

Aaron Samulcek
Interim President & CEO, Planned Parenthood Great Plains

Date: 10/25/2017

Dr. Orrin Moore, M.D.
Medical Director, Planned Parenthood Great Plains

Americans United for Life

[1] At the time of signing, the regulations at issue were proposed emergency rules (19 C.S.R. 10-15.050 and 10 C.S.R. 30-30.061). This agreement will remain in force if and when those rules become effective.

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Orrin A. Moore (ABMSUID - 3712) Viewed:5/9/2017 10:34:43 PM CST

DOB: 12/01/1942

Education: 1976 MD (Doctor of Medicine)

Address: 38 E 30th St
New York, NY 10016-7374 (United States)

Individual NPI [1]: 1053441659

Show Active Medical License(s) [2]:

Certification:

ABOG American Board of Obstetrics & Gynecology

Obstetrics & Gynecology - General ***Status: Certified***

Status	Duration	Occurrence	Start Date - End Date	Participating in MOC
Active	Lifetime	Initial Certification	11/05/1982 -	Not Required

Learn more about Obstetrics & Gynecology MOC program

[1] NPI: Not for Primary Source Verification (PSV).

[2] State of Licensure provided by Federation of State Medical Boards (FSMB): Not for Primary Source Verification (PSV).

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Notice: It is up to the user to determine if the physician record obtained from this service is that of the physician being sought.

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Ronald Norman Yeomans (ABMSUID - 424462) Viewed:8/17/2017 10:37:08 PM CST

DOB: 12/08/1940

Education: 1967 MD (Doctor of Medicine)

Address: Comp Hlth Women
4401 W 109th St
Overland Park, KS 66211-1303 (United States)

Individual NPI [1]: 1417018557

Show Active Medical License(s) [2]:

Certification:

ABOG American Board of Obstetrics & Gynecology

Obstetrics & Gynecology - General ***Status: Certified***

Status	Duration	Occurrence	Start Date - End Date	Participating in MOC
Active	Lifetime	Initial Certification	1975 -	Not Required

Learn more about Obstetrics & Gynecology MOC program

[1] NPI: Not for Primary Source Verification (PSV).

[2] State of Licensure provided by Federation of State Medical Boards (FSMB): Not for Primary Source Verification (PSV).

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Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

July 18, 2018

Amanda Addison, VP of Operations (via e-mail: Amanda.addison@ppgreatplains.org)
Planned Parenthood Great Plains
1001 Emanuel Cleaver II Blvd
Kansas City, MO 64110

Regarding: Midtown Health Center-Patty Brous Center Inspection results (FID: #A005)

Dear Ms. Addison:

Your facility currently has an Abortion Facility license that expires August 10, 2018. 19 CSR 30-30.050(2)(I) states "No license shall be issued or renewed by the department until the department has inspected the facility and determined that it is in compliance with all requirements of applicable regulations and statutes."

Representatives of the department conducted an inspection of the facility ending June 21, 2018. During the inspection it was determined that the facility has not performed any abortion procedures since March 29, 2018. There is not currently an approved physician available to perform abortions at the facility, nor any immediate plans to have one in place prior to the expiration of the license.

As a result of this lack of a physician, and as the facility is not currently capable of performing abortion procedures in compliance with all applicable statutory and regulatory requirements, a complete inspection could not be conducted.

Unless the facility can actively demonstrate compliance with all rules, and is again actively performing abortion procedures prior to the upcoming license expiration date, the Abortion Facility license cannot be renewed. Please inform the department as soon as possible prior to the expiration date if a new physician is acquired, a newly approved complication plan is in place, and when the facility can fully demonstrative compliance.

Note: If the current license expires, you may re-apply for a new license in the future when the facility is again able to demonstrate compliance with all applicable statutes and rules.

In addition to the issues related to lack of a physician, attached is a list of other findings (Statement of Deficiencies) that must be addressed and verified in compliance prior to a license renewal. Please respond in writing within ten (10) calendar days from receipt using the attached Plan of Correction (POC) template.

If you have additional questions do not hesitate to contact our office at BAC@health.mo.gov or via phone at 573-751-6083.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care

Americans United for Life

MO Bureau of Ambulatory Care—Facility Plan of Correction (POC) Form

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Midtown Health Center (a/k/a Patty Brous Health Center)	Survey Exit Date (from CMS 2567)	June 21, 2018
Facility Address/ City/Zip	1001 Emanuel Cleaver II Blvd, Kansas City, MO 64110	State or Federal SOD Q-tags, L-tags, K-tags, E-tags	L000, L1072, L1076, L1081, L1084, L1090, L1101, L1104, L1109, L1113, L1118, L1120, L1122, and L1194

1. Include a copy of the first page of *each* of the original forms CMS-2567 Statement(s) of Deficiencies for Federal (Q-tags), State (L-tags), Life Safety (K-tags) and Emergency Preparedness (E tags) ***signed & dated by administrator*** or designee, along with associated completed POC forms no later than ten (10) calendar days from receipt. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-6083. Our fax number is 573-751-6158.

2. Complete a **separate POC form for each applicable regulation set of the Statement of Deficiencies** (federal Q tags, state L tags, Life Safety K tags and Emergency Preparedness E tags).

3. Required elements of an acceptable Plan of Correction. Chapter 2 of the State Operations Manual (2728B) describes necessary elements for an acceptable POC. **Each** deficiency shall be addressed separately by completing the applicable information for **each** element below for **every** citation for Q-tags, L-tags, K-tags and E tags.

   A: Indicate the prefix or Tag number for each citation indicated on the form CMS-2567 "Statement of Deficiencies" (Q001, L125, etc)

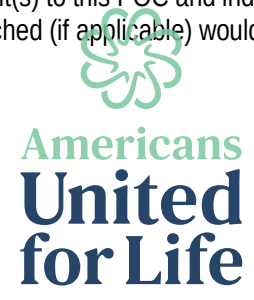
   B: Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete.

   C: For each deficiency, indicate date correction will be made or all components for correction put in place. Can NOT be prior to the Exit Date, and generally must be no later than 60 days from receipt of the CMS-2567, per 42 CFR 488.28. *(Limited extensions may be granted upon written request should extraordinary circumstances exist.)* To maximize correction opportunities, correction should be less than 45 days from Exit. Note: the monitoring required in "E" below will generally extend past this date.

   D: For each deficiency, include the Title of the person responsible for implementing the plan of correction for each deficiency.

   E: Describe the monitoring and/or tracking procedure that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. If the person responsible for ongoing monitoring is different than the person named in "D," note it here.

   F: Evidence/Exhibit attachment(s). Each POC form should stand on its own, and Element B should fully explain the actions the facility has taken or will take. Although not formally part of the POC, if written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A". Examples of routine exhibits expected to be attached (if applicable) would be:
   F1: Copies of applicable portions of any revised/amended facility policy to address the deficiency.
   F2: In-service/staff training attendance sheets.
   F3: Work orders or equipment service reports.
   F4: Meeting minutes or QA monitoring tools.



A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L000	As L000 includes only background information and initial comments, CHPPGP offers no plan of correction.	N/A	N/A	N/A	N/A

A	B	C	D	E	F
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L1072	CHPPGP objects to the deficiency identified in L1072 as it appears to require that the administrator of an abortion facility must be present even when the building is being operated as a family planning clinic by a different entity, Planned Parenthood Great Plains ("PPGP"). PPGP is not licensed to and does not operate an abortion facility; therefore, it cannot be required to have on-site an administrator of an abortion facility. CHPPGP offers the following response to each finding contained within L1072: 1. As stated on the designation of the acting administrator form produced to DHSS, the designation applies to CHPPGP, not PPGP. 2. When DHSS arrived for its inspection, PPGP was operating the facility as a family planning clinic. No abortions were being provided or, as DHSS notes, had been provided for a period of months. The then-administrator of CHPPGP's Kansas City abortion facility, along with the designated acting administrator for times when the administrator was unavailable, went to the facility to make themselves available to inspectors, even though CHPPGP was not in operation on that date. 3. DHSS cites no regulation that requires a non-abortion facility to abide by abortion facility requirements.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

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A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	CHPPGP notes that it has selected a new administrator for its abortion facility, and it will ensure that employee – or the employee designated to act as administrator in her absence – will be on-site for any dates on which CHPPGP operates the Kansas City facility.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1076	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. For clarification of DHSS's findings, CHPPGP notes that at no time did it offer abortion care without a qualified provider.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1081	CHPPGP will conduct future drills to include both part-time ("PRN") employees and temporary contractors, if applicable, to ensure that all employees who may be on-site when CHPPGP is operating the Kansas City facility are prepared for evacuation during a disaster. CHPPGP will conduct two additional drills in the next 45 days to ensure all employees participate.	Two drills will be conducted by 9/13/18. CHPPGP employees at the KC facility will participate in at least one of those drills.	Facility Administrator	Administrator will review the current written plan for evacuation of patients and personnel in the event of a fire, explosion, active shooter or other disaster with VP of Health Services. She will then conduct two evacuation drills prior to September 13, 2018. All CHPPGP employees of the KC facility will participate in at least one of those drills.	N/A

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP will take the following steps in response to the items identified in this finding: 1. **Arrange an in-person meeting with its environmental services cleaning provider to review its expectations and standards**. Facility Administrator, Regional Director of Health Center Operations, and Vice President of Operations, will attend the meeting and review with the environmental services provider each of the areas identified in DHSS's report. This step is designed to address the dust-related portions of the finding. 2. **Document on a log the daily inspection performed by personnel at the KC facility prior to seeing patients.** The log will be maintained for 30 days by Administrator and submitted to Regional Director for review. This step is designed to address the dust-related portions of the finding. 3. **Administrator and VP of Operations will review with CHPPGP's facilities coordinator the following issues**: 1) chipped or peeling laminate and the sink in Observation 5; the cabinet doors with labels and/or adhesive tabs in Observation 6; and the cabinet under the sink, the cabinet under the sterilizer and the upper cabinets with labels and/or adhesive in Observation 7. The	Item 1 will occur within 30 days of the submission of this POC. Item 2 will commence on 8/15/18, be evaluated daily, and conclude on 9/14/18. The meeting outlined in Item 3 will be concluded by 8/20/18, and repairs/replacements will be	Vice President of Operations	Item 1, a one-time meeting, will be monitored by Facility Administrator and Regional Director. Item 2 will be monitored on a daily basis by Facility Administrator and on a weekly basis by Regional Director. Item 3 will be monitored by VP of Operations. In addition to scheduling the initial meeting prior to 8/20/18, VP of Operations will oversee repairs and/or replacements, as necessary.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	facilities coordinator will outline a process for repair and/or replacement for those items. 4. The disposable pad identified in Observation 5 has been removed, and instruments will be placed directly on the cart in the future. CHPPGP seeks to clarify that, to the extent any employee interviewed by DHSS surveyors described the cessation of abortion services on a date different than reflected in electronic health records, such errors were caused only by employees' attempts to recall specific dates that were months prior to the unannounced inspection. CHPPGP made no attempt to prevent disclosure of dates on which abortions were performed and permitted DHSS to review requested records from any and all dates on which abortions were provided. Additionally, CHPPGP completes intentional termination of pregnancy (ITOP) reports on a monthly basis and provides those reports to DHSS. The KC facility's ITOP reports reflect that the most recent procedures were performed on March 29, 2018. CHPPGP notes that, as part of the items reviewed for the L1084 finding, the surveyor cited to Recommendation II.a of AORN's "Guideline for Environmental Cleaning." One portion of that guideline specifically described procedures for a "surgical environment" in which "an operative or invasive procedure" was being conducted. As DHSS is aware, CHPPGP does not perform any surgical	concluded by September 14, 2018.			

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	procedures at its Kansas City facility and is licensed to provide medication abortion procedures.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1090	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. For clarification of DHSS's findings, CHPPGP notes that at no time did it offer abortion care without a qualified provider. Additionally, CHPPGP notes that, at all times during which it operated in 2017-2018, at least one licensed employee with current CPR training was onsite. Specifically, a DHSS surveyor reviewed the personnel file for the physician who provided abortion care at the Kansas City facility in 2017 and 2018. That file reflected that the provider had current CPR certification.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1101	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. CHPPGP is unable to provide additional responsive information, as this finding did not identify any specific instances in which CHPPGP was *not* in compliance; instead, it stated only that it could not be evaluated.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1104	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. CHPPGP notes that, although personnel reported that no ultrasound machine was at the facility on the date of the inspection, its machine will be returned to the Kansas City facility prior to resuming abortion services. DHSS did not identify any abortions provided since the Kansas City facility received its license in 2017 that lacked ultrasound images in patients' electronic health records. CHPPGP is unable to provide additional responsive information, as this finding did not identify any specific instances in which CHPPGP was *not* in compliance; instead, it stated only that it could not be evaluated. Additionally, as noted by DHSS in its findings, CHPPGP did not provide abortion services during the period in which the certification/training requirement for ultrasound-performing personnel was in effect.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1109	CHPPGP objects to the deficiency identified in L1109 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that each patient receiving abortion care is provided with discharge instructions that include the following hand-outs: 1) How to Take the Pills for Your Abortion and What to Expect; and 2) Taking Your Abortion Pills (with specific information for each patient). DHSS's report does not state, however, that an entry is made by CHPPGP personnel in each patient's medical record that the patient received copies of those documents. That entry satisfies the regulation's requirement that written discharge instructions be provided to patients.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1113	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061. CHPPGP is unable to provide additional responsive information, as this finding did not identify any specific instances in which CHPPGP was *not* in compliance; instead, it stated only that it could not be evaluated.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1118	CHPPGP objects to the deficiency identified in L1118, as DHSS's interpretation of the regulatory language appears to contradict the plain language (and intent) of state law. The daily roster produced by CHPPGP to the surveyors included patients in the following three categories: 1) patients meeting with CHPPGP personnel for state-mandated consent visits to begin the 72-hour waiting period; 2) patients scheduled to have an abortion procedure; and 3) patients returning to the facility for a follow-up visit after having an abortion procedure. CHPPGP interprets the term "abortion services," as used in 19 CSR 30-30.060(3)(A) to include *all patients* in those three categories, as DHSS and the State of Missouri regulate elements of each of those visits. If DHSS wishes to change its interpretation of the regulation (and state law) such that neither the mandated consent visit nor follow-up care is included in the regulation's description of "abortion services," CHPPGP will produce a different roster. To the extent DHSS intends to continue imposing regulations that relate to both the mandated consent visit and follow-up care to an abortion procedure, CHPPGP will maintain a daily roster with all three types of visits. CHPPGP is willing to work to identify an alternative way of pulling a daily roster from its electronic health	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	records that reflects only patients scheduled for an abortion procedure on a given day; however, that process is intended only for the convenience of surveyors and not for compliance with 19 CSR 30-30.060(A), for the reasons outlined above.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1120	CHPPGP objects to the deficiency identified in L1120 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that the physician providing care signed and dated the visit summary generated by the electronic health record, which reflects the medications prescribed during the patient encounter. To CHPPGP's knowledge, DHSS has never previously interpreted this regulation to require *each separate portion* of a patient's medical record be signed and authenticated by the treating physician. CHPPGP will, however, seek to alter the layout of its electronic health record to create an additional place for the physician to sign, date, and time medication orders for each patient. This entry will be duplicative of that information on the patient's visit summary.	CHPPGP will work with the software provider for its electronic health records system to implement this change by September 14, 2018.	Vice President of Operations	VP of operations will work with the software provider to ensure the electronic records template is changed by September 14, 2018. Facility Administrator will review electronic health records for all patients receiving abortion care for one month after the revised template becomes effective to monitor for compliance.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1122	CHPPGP objects to the deficiency identified in L1122 to the extent it misstates the nature of the information conveyed during the survey process. For each of the patient records reviewed by the surveyor, a physician or qualified health professional (as defined by § 188.027, RSMo) provided the state-mandated information to patients receiving abortion care. The records described in L1122 reflected that persons meeting the statutory and regulatory definitions gave the required information. DHSS's interpretation appears to be that CHPPGP is *prohibited* from providing any additional information, including education, to patients by trained personnel who do not meet the statutory definitions. Upon questioning a DHSS surveyor, CHPPGP staff were informed that the facility's current practice "complied with the law but not the regulation." That response provides no guidance to CHPPGP, and CHPPGP is unwilling to limit the factually accurate information it provides to patients, particularly when it provides the required information by personnel who meet the state's definitions. Personnel who do not meet the statutory or regulatory definitions of "qualified professional" are available to reiterate portions of the information also provided by physicians or "qualified professionals," outlining alternatives to abortion and reiterating that a physician is available to answer patient questions.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	It is CHPPGP's position that providing information from multiple sources is the most efficient, patient-centered approach possible, and it is committed to continuing that practice.				

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1194	CHPPGP has arranged for a qualified physician to offer abortion care. It has, as part of its annual license renewal, submitted the relevant information to DHSS, along with a proposed complication plan to comply with § 188.021, RSMo, and 19 CSR 30-30.061.	CHPPGP is in compliance as of July 26, 2018, the date on which it submitted its license renewal.	Vice President of Health Services	CHPPGP's agreement with its new physician has no set end date; however, if any change in provider occurs, CHPPGP will submit a complication plan to DHSS and, upon approval, notify the department of the change of provider.	*See* CHPPGP's license renewal application, submitted to DHSS on 7/26/2018.

Americans United for Life

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

January 30, 2019

Amanda Addison, R.N, BSN, MBA, VP of Operations
Comprehensive Health of Planned Parenthood Great Plains, Inc.
1001 Emanuel Cleaver II Blvd.
Kansas City, MO 64110

Dear Ms. Addison:

The Department conducted an annual licensure inspection of Comprehensive Health of Planned Parenthood Great Plains, Inc. in Kansas City on June 21, 2018. At that time, it was determined that your agency had not conducted an abortion since March 2018, due to lack of physician services. As a result, compliance with several legal and regulatory requirements could not be verified.

In August 2018, your agency received approval of a newly submitted complication plan, based on your acquisition of physician services provided by Dr. Coleen McNicholas. The Department conducted a revisit of your agency on September 19, 2018, and found that your agency was in compliance with legal requirements at that time (see attached Statement of Deficiencies).

During the September revisit to your agency, Dr. McNicholas informed Department staff that she was in the process of seeking privileges at Menorah Medical Center (Overland Park, KS), in accordance with the licensure requirements outlined in Chapter 188.027, 188.080, 197.215 and 19 CSR 30-30.060 (1)\(C)(4). She further stated that she expected the privileges to be granted no later than January 2019.

The purpose of this letter is to seek an update as to Dr. McNicholas' progress towards obtaining the required privileges. At your earliest convenience, please contact me at 573-751-1588 to discuss this matter.

Respectfully,

Melinda Laughlin, Chief
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 20, 2018

Brie Anderson
Vice President for Health Services
Comprehensive Health of Planned Parenthood Great Plains, Inc.
4401 W. 109th Street, Suite 200
Overland Park, Kansas 66211

Via email to: Brie Anderson@ppgreatplains.org

RE: Complication plan submitted for Comprehensive Health of Planned Parenthood Great Plains, Inc., located at 1001 Emanuel Cleaver II Blvd., Kansas City, MO 64110

Ms. Anderson:

This letter serves as written approval of the proposed complication plan, submitted to the DHSS on July 26, 2018, for the above referenced facility.

Please be advised that the facility license (17-2) expired on August 10, 2018, and no abortions may be performed until such time as DHSS verifies compliance with the provisions of applicable abortion laws through an onsite inspection. A representative of the DHSS will contact you in order to schedule an initial inspection.

Sincerely,

William Koebel
Section Administrator
Section for Health Standards and Licensure

cc: vicki.casey@ppgreatplains.org

Americans United for Life

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, INC.

Department of Health and Senior Services Complication Plan

DIVISION:	Health Services	**EFFECTIVE DATE:**	July 26, 2018
WORK PRACTICE:	DHSS Medical Abortion Complication Plan	**NUMBER OF PAGES:**	3
DOCUMENT RELATED TO:	§ 188.021, RSMo, and 19 CSR 30-30.061		
FACILITY LOCATION:	Comprehensive Health of Planned Parenthood Great Plains, Inc. (CHPPGP) – Kansas City facility		

I. Purpose

This plan is submitted in order to comply with § 188.021, RSMo, and 19 CSR 30-30.061, which require that facilities licensed to perform abortions must have in place a complication plan that meets certain standards.

II. Facility Physicians

This plan applies to CHPPGP's licensed abortion facility in Kansas City (the Patty Brous facility). The physician performing medication abortions in Kansas City (Dr. Colleen McNicholas, D.O.) is board-certified by the American Board of Obstetrics and Gynecology. In addition to this physician, CHPPGP's Medical Director (Dr. Orrin Moore, M.D.) is board-certified by the American Board of Obstetrics and Gynecology. Dr. Moore has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center. Whenever possible, Dr. McNicholas will personally treat complications experienced by her medication abortion patients. When Dr. McNicholas is unavailable to treat complications, Dr. Moore shall personally treat complications 24/7 relating to medication abortions, including by providing surgical follow-up care. If Dr. Moore is ever unavailable to treat complications, Dr. Ronald Yeomans, M.D., who is also board-certified by the American Board of Obstetrics and Gynecology, shall personally treat complications 24/7 during Dr. Moore's period of unavailability. Dr. Yeomans has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

III. Treatment of Complications

CHPPGP maintains an answering service for which a nurse (RN, LPN, or NP) is on call 24/7 to address patients' questions and concerns. A board-certified OB/GYN physician is available to the on-call nurse 24/7 to respond to questions and determine plan of care, if necessary.

Patients who have a medication abortion must receive written post-abortion care instructions that:

- provide signs and symptoms of problems to watch for;
- instruct patients on what to do if a problem occurs, including when to contact the on-call nurse; and
- provide the phone number of the answering service to reach the on-call nurse.

COMPREHENSIVE HEALTH OF PLANNED PARENTHOOD GREAT PLAINS, INC.

Department of Health and Senior Services Complication Plan

When a patient calls the 24/7 answering service, the call will be forwarded to the on-call nurse. The on-call nurse must be trained to assess each patient individually and identify and manage problems the patient may be experiencing, in accordance with established protocols.

After the patient is personally assessed, and if the on-call nurse and/or the on-call OB/GYN physician determines that follow-up care is needed, the patient will be directed to return to a health center to receive such care. If a patient requires follow-up care from a physician, Dr. McNicholas, Dr. Moore, or Dr. Yeomans will personally treat complications relating to medication abortions, including those requiring surgical intervention, which were provided to patients at the Patty Brous facility.

However, if after the patient is personally assessed and if the on-call nurse and/or Dr. McNicholas, Dr. Moore, or Dr. Yeomans determines that it is not in the patient's best interest or it would not be in accordance with the standard of care for the patient to receive follow-up treatment from Dr. McNicholas, Dr. Moore, or Dr. Yeomans, the patient will be instructed to go to her nearest emergency room. The patient must be instructed to take with her to the emergency room the written take-home instructions that were previously provided to her, which explain that the patient received abortion care, and encourages the emergency room to contact the 24/7 answering service. The patient must also be instructed to call the on-call nurse once she arrives at the emergency room.

The on-call nurse must not, as a matter of course, call the emergency room in advance without the patient's consent in order to protect her confidentiality and privacy, as the patient may decide to go to a different hospital for a variety of reasons (such as financial issues, insurance coverage, or concerns about confidentiality).

Once the patient arrives at the emergency room, she or, with the permission of the patient, the attending physician or other clinician managing her care should call the CHPPGP on-call nurse so that the attending physician or other clinician managing the patient's care can be briefed on the care the patient received.

On-call nurses document each call, including those that do not involve complications, and enter notes into patient records. The on-call nurses maintain communication with each other regarding patients who were assessed and require follow-up care.

IV. Follow-up Care

In the event the on-call nurse advises a patient to seek emergency care, a follow-up call is made by CHPPGP to that patient within 24 hours. The follow-up call is to be documented in NextGen.

V. Reporting

The OB/GYN treating a patient's complication shall prepare a complication report as required by § 188.052, RSMo, and ensure that the report is submitted to the Missouri Department of Health and Senior Services and placed in the patient's medical record.

VI. Covered Physicians

The CHPPGP physician covered by this plan is Dr. Colleen McNicholas, D.O. The OB/GYN providing 24/7 back-up complication coverage is Dr. Orrin Moore, M.D. Dr. Ronald Yeomans, M.D., has agreed to provide 24/7 back-up complication coverage in any instance in which Dr. Moore is unavailable. A copy of the written agreement between CHPPGP and Drs. Moore and Yeomans is attached to this plan, along with a copy of the OB/GYN board certification credentials profiles for Drs. McNicholas, Moore, and Yeomans.

Memorandum of Understanding

Between Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP")
and Drs. Orrin Moore, M.D., and Ronald Yeomans, M.D.

This Memorandum of Understanding (MOU) sets forth the terms and understanding between CHPPGP and Drs. Moore and Yeomans to establish a plan for back-up care for medication abortion patients at the Patty Brous health center in Kansas City, as required for compliance with the Missouri Code of State Regulations.

Purpose
To fulfill the requirements of 19 C.S.R. 10-15.050 and 19 C.S.R. 30-30.061, Dr. Moore agrees to serve as the 24/7 back-up physician to treat complications of medication abortion patients at the Patty Brous health center, including surgical follow-up. Dr. Moore will provide 24/7 back-up care when Dr. McNicholas is unavailable to treat complications for Patty Brous patients, except when it is determined that it is not in the patient's best interest or would not be in accordance with the standard of care.

Dr. Moore states that he is a board-certified OB/GYN who has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

At those times when Dr. Moore is unavailable to provide 24/7 back-up care, Dr. Ronald Yeomans agrees to serve as the 24/7 back-up physician to treat complications of medication abortion patients at the Patty Brous health center, including surgical follow-up. Dr. Yeomans will provide 24/7 back-up care when Dr. Moore is unavailable, except when it is determined that it is not in the patient's best interest or would not be in accordance with the standard of care.

Dr. Yeomans states that he is a board-certified OB/GYN who has admitting privileges at a full-service, acute care hospital located within 30 miles of the Patty Brous health center.

Duration
This MOU shall become effective upon signature by the individuals named herein and will remain in effect until modified or terminated by either party or by mutual consent. The parties understand that, should they desire to alter this MOU, they will notify the Missouri Department of Health and Human Services.

Amanda Addison Date: 7/26/18
Amanda Addison
Vice President of Operations, Comprehensive Health of Planned Parenthood Great Plains, Inc.

Date: 7/26/2018
Dr. Orrin Moore, M.D.
Medical Director, Planned Parenthood Great Plains

Ronald W Yeomans, MD Date: 7/26/18
Dr. Ronald Yeomans, M.D.
Contract Physician, Planned Parenthood Great Plains

Americans United for Life

ABOG

American Board of Obstetrics + Gynecology

First in Women's Health

July 24, 2018

RE: Certification Status of Colleen P. McNicholas, D.O.

To Whom It May Concern:

Colleen P. McNicholas, D.O. is a Diplomate of the American Board of Obstetrics & Gynecology (ABOG).

Obstetrics and Gynecology Certification

ABOG ID Number: 9025020
Original Certification Date: 1/17/2014
Certification Status: Valid through: 12/31/2018
Participating in Maintenance of Certification: Yes

A physician becomes a Diplomate of the ABOG when he/she has fulfilled all requirements, has satisfactorily completed the written and oral examinations and has been awarded ABOG's certifying diploma.

Physicians certified by the ABOG in Basic Obstetrics and Gynecology prior to 1986 or subspecialty certified prior to November, 1987 hold non-time-limited (non-expiring) certificates. They are not required to participate in Maintenance of Certification.

Sincerely,

George D. Wendel, Jr. M.D.
Executive Director

Americans United for Life

2915 Vine Street, Dallas, Texas 75204 | P: 214.871.1619 | F: 214.871.1943 | E: info@abog.org | W: ABOG.org

A265980

ABOG

American Board of Obstetrics + Gynecology

First in Women's Health

July 24, 2018

RE: Certification Status of Orrin A. Moore, M.D.

To Whom It May Concern:

Orrin A. Moore, M.D. is a Diplomate of the American Board of Obstetrics & Gynecology (ABOG).

Obstetrics and Gynecology Certification

ABOG ID Number: 19102
Original Certification Date: 11/1/1982
Certification Status: Non-Expiring
Participating in Maintenance of Certification: Not required at this time

A physician becomes a Diplomate of the ABOG when he/she has fulfilled all requirements, has satisfactorily completed the written and oral examinations and has been awarded ABOG's certifying diploma.

Physicians certified by the ABOG in Basic Obstetrics and Gynecology prior to 1986 or subspecialty certified prior to November, 1987 hold non-time-limited (non-expiring) certificates. They are not required to participate in Maintenance of Certification.

Sincerely,

George D. Wendel, Jr. M.D.
Executive Director

Americans United for Life

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A139998

ABOG

American Board of Obstetrics + Gynecology

First in Women's Health

July 24, 2018

RE: Certification Status of Ronald N. Yeomans, M.D.

To Whom It May Concern:

Ronald N. Yeomans, M.D. is a Diplomate of the American Board of Obstetrics & Gynecology (ABOG).

Obstetrics and Gynecology Certification

ABOG ID Number: 7329
Original Certification Date: 1/1/1975
Certification Status: Non-Expiring
Participating in Maintenance of Certification: Not required at this time

A physician becomes a Diplomate of the ABOG when he/she has fulfilled all requirements, has satisfactorily completed the written and oral examinations and has been awarded ABOG's certifying diploma.

Physicians certified by the ABOG in Basic Obstetrics and Gynecology prior to 1986 or subspecialty certified prior to November, 1987 hold non-time-limited (non-expiring) certificates. They are not required to participate in Maintenance of Certification.

Sincerely,

George D. Wendel, Jr. M.D.
Executive Director

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A017121

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

October 18, 2017

Janice Thomas, Administrator < Janice.thomas@ppslr.org >
Reproductive Health Services of Planned Parenthood of the St. Louis Region
626 E. Battlefield
Springfield, MO 65807

Re: Reproductive Health Services of Planned Parenthood – Springfield facility inspection

Dear Ms. Thomas:

The Department of Health and Senior Services received an application for licensure of the Springfield Planned Parenthood location as an abortion facility. Bureau of Ambulatory Care staff conducted an onsite initial inspection of the facility on October 10th and 11th of this year, in order to determine compliance with applicable statutes and regulations in effect at the time of the inspection.

Listed below are items the survey indicated were not in compliance with current rules. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued.

The facility was found to be out of compliance with the following:

19 CSR 30-30.050 Definitions and Procedures for Licensing Abortion Facilities
(1)(C) 3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.

-For three of three physicians (Staff AA, BB, CC) there was no recommendation by the medical staff or approval by the governing body for the physicians to be on the medical staff at this facility.
-The credentialing packets were incomplete and did not include:
**Information for Physician staff AA and BB did not include privileges requested and approved;*
**Physician staff BB did not have a BNDD/DEA registration; and*
**Physician staff CC had a date of 05/02/17 on a credentialing sheet but it was unclear if the privileges and approval were for this facility.*
-The meeting minutes provided, dated 01/06/2016, did not include names of physicians or identification of this facility for the section where it mentioned approval of attending physicians.

19 CSR 30-30.060(1)(B)13 A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs).

- No criminal background check on three of six employee files reviewed.

19 CSR 30-30.060(1)(B)8 The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.

- Medication prep/storage area was located in the lab area and at risk for cross-contamination;
- Pressed-board clipboard at registration desk with un-cleanable surface;
- Expired urine test strips;
- No recent infection control training for two of six employee files reviewed;
- Examination table in the ultrasound exam room had rust along the front edge of the table. There was damage to the wood at the base of the table and missing laminate on the front of the table, exposing pressed wood. All of these items created un-cleanable surfaces, posing an infection control risk; and
- Examination room #4 had a high level chemical disinfectant in an instrument soaking container located next to the hand washing sink. Used vaginal ultrasound probes were cleaned in the hand washing sink and decontaminated with a high level disinfectant in the examination room. The facility failed to place the probe in a leak-proof container or plastic bag and transport it to the soiled utility room to be cleaned and decontaminated.
- There were no smoke detectors in the training room, laboratory, store room and three offices.

19 CSR 30-30.060(3)(L) Emergency drugs, oxygen and intravenous fluids shall be available in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine and endotracheal equipment shall be located in the clinical area for immediate access.

- No suction machine; and
- No endotracheal equipment.

19 CSR 30-30.060(3)(C) A medical history shall be obtained and a health assessment including a pelvic examination shall be performed. There must be confirmation of pregnancy by clinical evidence and laboratory tests. The findings shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's chart.

***-** The facility failed to have policies and procedures in place that addressed pelvic examinations for medication abortions.*

19 CSR 30-30.060(4)(D) The following laboratory procedures shall be performed on every abortion patient: hematocrit; urinalysis, including pregnancy test; and Rh typing.

- The facility failed to stock the glucometer control testing solutions used to verify the glucometer is functioning properly before use.

Please respond in writing, providing documentation that each of these items has been fully addressed and corrected. If you have further questions, contact our office at 573-751-6083 or via email at BAC@health.mo.gov. Only upon successful completion of the revisit process can an abortion facility license be issued.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

December 21, 2017

Janice Thomas, Administrator *via email to*: < Janice.thomas@ppslr.org >
Reproductive Health Services of Planned Parenthood of the St. Louis Region
626 E. Battlefield
Springfield, MO 65807

Re: Reproductive Health Services of Planned Parenthood – Springfield facility inspection

Dear Ms. Thomas:

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(1)(C) 3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.

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- Examination room #4 had a high level chemical disinfectant in an instrument soaking container located next to the hand washing sink. Used vaginal ultrasound probes were cleaned in the hand washing sink and decontaminated with a high level disinfectant in the examination room. The facility failed to place the probe in a leak-proof container or plastic bag and transport it to the soiled utility room to be cleaned and decontaminated.
- There were no smoke detectors in the training room, laboratory, store room and three offices.
- The facility failed to stock the glucometer control testing solutions used to verify the glucometer is functioning properly before use.

19 CSR 30-30.060(3)(L) Emergency drugs, oxygen and intravenous fluids shall be available in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine and endotracheal equipment shall be located in the clinical area for immediate access.

- No suction machine; and
- No endotracheal equipment.

19 CSR 30-30.060(3)(C) A medical history shall be obtained and a health assessment including a pelvic examination shall be performed. There must be confirmation of pregnancy by clinical evidence and laboratory tests. The findings shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's chart.

- *The facility failed to have policies and procedures in place that addressed pelvic examinations for medication abortions.*

Note: In addition to the above items, since the date of the onsite visit, the department promulgated emergency rule ***19 CSR 30-30.061, Complication Plans for Certain Drug and Chemically Induced Abortions via Abortion Facilities***. This emergency rule was effective 11/3/17. To date, your facility has not submitted a proposed Complication Plan. Since the facility's plan is to perform only medication abortions for the time being, until your facility becomes compliant with that rule, the facility cannot be licensed as an abortion facility.

Please respond in writing, providing documentation that each of these items has been fully addressed and corrected. If you have further questions, contact our office at 573-751-6083 or via email at BAC@health.mo.gov . Only upon successful completion of the revisit process can an abortion facility license be issued.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

March 29, 2018

Janice Thomas
VP of Patient Services & Research
Reproductive Health Services of Planned Parenthood
4251 Forest Park Avenue
St. Louis, MO 63108

Via email to Janice.Thomas@ppslr.org

Re: Proposed complication plan for Springfield, Missouri facility

Dear Ms. Thomas:

The proposed complication plan submitted by Reproductive Health Services of Planned Parenthood for the Springfield facility on January 8, 2018, does not meet the requirements of Section 188.021, RSMo, and 19 CSR 30-30.061 in that:

The plan states that Dr. Grebe, a board-certified OB/GYN, will provide medical abortions in Springfield and treat the complications whenever possible. Whenever not possible, the plan states that either Dr. David Eisenberg or Dr. Orrin Moore respectively will personally treat complications at the Reproductive Health Services (RHS) facility in St. Louis or at a Comprehensive Health facility in Overland Park, Kansas. Dr. Eisenberg and the RHS facility are located over three hours driving time from the Springfield facility. Dr. Moore and the Overland Park facility are located over two-and-a-half hours driving time from the Springfield facility. As a result, neither Dr. Moore nor Dr. Eisenberg will be available to personally treat all complications in Dr. Grebe's absence, and patients who are not experiencing immediately life-threatening complications will be referred to the emergency room.

Additionally, the proposed plan fails to recognize the importance of the physician-patient relationship by providing for continuity of care and ensuring communication among the physician who induced the abortion and all subsequent health care providers involved in treating the patient's complication.

Because the facility's proposed plan does not meet the requirements of Section 188.021, RSMo, and 19 CSR 30-30.061, the Department cannot approve the plan. Accordingly, the Department cannot issue the facility a license until an approved plan is in place (and all other deficiencies have been corrected).
If the facility wishes to submit a new or revised plan, please send it to the Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102, or by email to John.Langston@health.mo.gov by April 15, 2018.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired: 1-800-735-2466 VOICE: 1-866-735-2460

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

June 1, 2018

Janice Thomas, VP of Patient Services & Research
Reproductive Health Services/
Planned Parenthood of the St Louis Region and Southwest Missouri
4251 Forest Park Ave, St. Louis MO 63108

Regarding Applications as Abortion Facilities for:

Springfield Planned Parenthood Clinic
626 East Battlefield
Springfield MO 65807

Joplin Planned Parenthood Clinic
710 Illinois Avenue
Joplin MO 64801

Janice Thomas:

1. During an interview on 5/29/2018 and confirmed on 5/30/18, St. Louis Planned Parenthood administrative staff stated that current plans to license the Springfield and Joplin locations as Abortion Facilities were indefinitely on hold.

2. By convention, the Bureau of Ambulatory Care holds applications open for new facilities for up to one year before requiring a new application package be submitted. The applications for the Springfield and Joplin locations were received by the Department of Health & Senior Services on 5/25/17, just over one year ago.

3. An initial inspection for the Springfield location was conducted October 2017. To date, an acceptable plan of correction for the items cited during that inspection has not been received. Moreover, a complete set of revised rules for abortion facilities went into effect on 4/30/2018, which would require a new inspection.

Due to the above items, the Bureau of Ambulatory Care is hereby closing the open Abortion Facility applications for the Springfield and Joplin Planned Parenthood Clinics. You may submit new applications at any point you believe the facilities are prepared to be in compliance with all applicable laws and rules for Abortion Facilities in Missouri.

If you have additional questions, do not hesitate to contact our office via email at BAC@health.mo.gov or by phone at 573-751-6083.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Planned Parenthood®
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Planned Parenthood of the St. Louis Region and Southwest Missouri

Administrative Office
4251 Forest Park Avenue
St. Louis, MO 63108
p: 314.531.7526 | f: 314.531.9731
www.plannedparenthood.org/stlouis

February 1, 2019

Via email to: William.Koebel@health.mo.gov

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: *Request for Deviation*

Dear Mr. Koebel:

Pursuant 19 CSR 30-30.070(2), I write to request deviations/waivers of certain physical standards for Reproductive Health Services of Planned Parenthood of the St. Louis Region's (RHS) health center in Springfield.

The physical facility restrictions in 19 CSR 30-30.070 prevent us from providing surgical abortion in our Springfield health center. RHS remains committed to providing abortion services to the women of Southwest Missouri, and therefore by this letter seeks waivers of those requirements it cannot meet. We request the Department "exercise[] the Waiver Provision" "with sufficient flexibility" and reasonableness. *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, 903 F.3d 750, 756–57 (8th Cir. 2018).

Abortion Safety

As you know, RHS has safely provided abortion services in Missouri for many years. The physical facility restrictions are medically unnecessary and do not improve the health and safety of our patients seeking abortion care. Indeed, the Department has recognized as much when it waived a number of medically unnecessary restrictions in a 2010 settlement with the Columbia health center.

Abortion is one of the safest medical procedures in the United States. As the National Academies of Sciences, Engineering, and Medicine—which recently conducted a systematic review of the safety and quality of care of abortion in the United States—found, abortion in the United States is safe. In particular, first-trimester aspiration

abortion, which we seek to provide in the Springfield health center, "is a minimally invasive and commonly used gynecological procedure," including "in cases of early pregnancy loss (miscarriage)."[1] Aspiration abortion is effective at terminating an early pregnancy in more than 99% of those provided, and complications from first-trimester aspiration abortion occur in approximately 1.26% of patients—and serious complication in less than 0.02%.[2] Aspiration abortion may require no or only minimal sedation.

As the National Academies observed, "[a]spiration abortions are performed safely in office and clinic settings."[3] Abortion-specific regulations—such as the physical facility restrictions in 19 CSR 30-30.070—serve only to "diminish" the quality of care women receive by "limit[ing] the number of available providers."[4]

Requested Waivers

Against the backdrop of abortion's demonstrated safety, and given that the current facility is sufficient to protect patient health and safety, we make the following waiver requests. We note at the outset that we are committed to working with the Department on these issues so that we can begin providing abortion services to our patients at the Springfield health center. We also note that the Springfield facility meets many of the requirements in 19 CSR § 30-30.070(4), which applies to facilities existing at the time the regulation was adopted, and therefore, demonstrates the Department's understanding that these provisions are sufficient to protect patient health and safety.

1. **Patient-Serving Corridors and Doors**

Subsections 30-30.70(3)(B) & (C) require patient-serving corridors be at least 6' wide and doors through which patients pass be at least 44" wide and of solid-core construction. Patient-serving corridors at the Springfield center are 4'7" wide and doors through which patients pass are at least 32" wide and of hollow-core construction.

The Springfield health center's current system of corridors and doors adequately protect patient health and safety by allowing a patient to be moved by stretcher from any point in the facility to the outside via the main entrance. Indeed, the Springfield health center's current corridors and doors comply with the requirement at 19 CSR § 30-30.070(4)(B) that the system of corridors and passageways be "adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit." We also note that the Department agreed to a similar corridor dimension for the Columbia health center in a 2010 settlement agreement.

[1] Nat'l Acad. of Sciences, Engineering & Medicine, The Safety and Quality of Abortion Care in the United States 2-12 (2018).
[2] *Id.* at 2-12 to 2-13 (citing Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 124 Obstetrics & Gynecology 175 (2015)).
[3] *Id.* at S-8.
[4] *Id.* at S-10.

2. Construction Type

Subsection 30-30.70(3)(D) requires one-story buildings be at least of Type II (111) protected noncombustible construction as described in *Standard on Types of Building Construction* 1979 published by the National Fire Protection Association. The Springfield facility is of Type V (100) unprotected combustible construction.

The Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The higher fire-safety rating is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

3. Fire Alarm

Subsection 30-30.70(3)(H) requires a manual fire alarm break station be located near each exit and connected to a local audible alarm that can be heard throughout the facility. The Springfield health center does not have manual fire alarm break stations at each exit.

The Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The requirement is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

4. Scrub Station

Subsection 30-30.70(3)(L) requires a scrub-up facility be knee- or foot-operated and be located outside the procedure room. The Springfield health center has a scrub station located inside the procedure room. The requirement that the scrub station be located outside the procedure room does not protect patient health or safety. The Springfield

center complies with the requirement in 19 CSR § 30-30.070(4)(F) that the scrub-up facility be located convenient to the procedure room.[5]

5. Procedure Room

Subsection 30-30.70(3)(M) requires that all procedure rooms be a minimum of 12' length and width, 9' ceiling height, and doors with a width of at least 44". The Springfield facility's procedure room's dimensions are 12'6" by 11'6", ceiling height of 7'9", and door width of 36".

The dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

Further, the Springfield health center's existing procedure room meets the requirement at 19 CSR § 30-30.070(4)(E) that it be "adequately equipped, supplied, and staffed to safely perform abortions," which the Department has determined is sufficient to protect patient health and safety; this requirement does not specify minimum dimensions. The room is of sufficient size to fit a gynecologic examining table with accessories, a closed cabinet for equipment, and tables to hold an emergency tray and other necessary equipment.

Requiring compliance with the nine-foot ceiling height would not advance patient health and safety, because such ceiling height requirements generally are intended to facilitate installation of a ceiling-mounted surgical light. These lights would not be appropriate to the procedures done at the Springfield health center, for the reasons given below under request no. 9. Requiring compliance with the 44" door width would not advance patient health and safety at the Springfield health center because, as discussed above under request no. 1, the current system of corridors and doors allows rapid patient evacuation in the event of an emergency. Finally, we note that the Department agreed to similar dimensions of 12' length, 9' 0.5" width, and 8' 6'" height for the Columbia health center in a 2010 settlement agreement.

6. Recovery Room

Subsection 30-30.70(3)(N) requires the recovery room be of sufficient size for four recovery recliners or beds with 3' of clear space on both sides and at the foot of each recliner or bed.

The Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner. We do not anticipate scheduling—and will agree to not schedule—more patients than the recovery room can accommodate. We note that the Department recently approved a deviation from this requirement for the Columbia facility to permit three recliners.

[5] We acknowledge our current scrub sink is not knee- or foot-operated. We will replace the current sink with a knee- or foot-operated if the Department approves this waiver.

7. HVAC

Subsection 30-30.70(3)(O) requires the procedure and recovery rooms be provided with a minimum of six air changes per hour and filtered through a filter with at least a twenty-five percent (25%) efficiency rating. The Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. This requirement is not necessary for patient health or safety, particularly since surgical abortion does not require a sterile operating room environment, as demonstrated by its omission in 19 CSR § 30-30.070(4).

8. Personnel-Change Room

Subsection 30-30.70(3)(P) requires personnel-change rooms be provided for each sex, located convenient to the procedure room, and equipped with a toilet and lavatory. The Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory. We note that the Department agreed to a similar deviation for the Columbia health center in a 2010 settlement agreement.

9. Ceiling-Mounted Surgical Light

Subsection 30-30.70(3)(R) requires the the procedure room be equipped with a ceiling-mounted light. The Springfield facility's procedure room would be equipped with a walled-mounted surgical light, which is better angled for the procedures that would be provided. We note that the Department agreed to similar deviation for the Columbia health center in a 2010 settlement agreement.

10. Sterilizing Room

Subsection 30-30.70(3)(V) requires that air pressure in the sterilizing room be positive in relation to adjacent areas. The air pressure in the Springfield health center's sterilizing room is not positive in relation to adjacent areas. This requirement is not necessary for patient health or safety, as demonstrated by its omission in 19 CSR § 30-30.070(4).

11. Patient-Change Rooms

Subsection 30-30.70(3)(Y) requires there be at least two patient-change rooms with secure storage for personal effects. The Springfield facility has one patient-change room. We note that the Department agreed to deviation for the Columbia health center in a 2010 settlement agreement such that there could be one patient-change room if the patient traveled with her belongings in a secure container. We will agree to do the same or provide the patient with secure storage in the patient-change room.

Burdens

Complying with the physical facility requirements in 19 CSR 30-30.070 at our Springfield facility would be prohibitively expensive and burdensome. A recent survey of the facility by a licensed architect found that it would cost $2.26 million to remodel the Springfield health center to meet the requirements in 19 CSR 30-30.070, which is approximately the same amount to construct a new facility. Construction would take

approximately eight months to complete and include complete removal and installation of the roof and exterior walls. As a result, such construction would completely disrupt the critical health services currently provided there, including family planning services that help prevent unplanned pregnancies.

Please let me know if you have any questions regarding this request. I look forward to hearing your prompt response.

Sincerely,

Janice Thomas
Vice President of Patient Services & Research

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

April 18, 2019

Cathy Williams, Interim President & CEO
Reproductive Health Services of Planned Parenthood
425 Forest Park Avenue
St. Louis, MO 63108

Re: Request for Deviation (RHS Health Center – Springfield, MO)

Dear Ms. Williams:

On February 1, 2019, Reproductive Health Services (RHS) submitted a Request for Deviations from some requirements of 19 CSR 30-30.070, for RHS' health center in Springfield, Missouri (attached).

The Department requested that RHS provide a code review sheet and architectural plans, as the request lacked sufficient information for DHSS to reasonably approve or deny the requests. In response, on February 8, 2019, RHS provided a facility floor plan (attached). The additionally provided information remained insufficient to make a determination. A mutually agreeable onsite walk-through was arranged for March 5, 2019, in order to gather sufficient information to respond to the submitted request.

On March 5, 2019, DHSS staff conducted a walk-through of the Springfield facility. RHS facilities manager, Chris Trull, represented RHS. The walk-through identified additional concerns related to the initial request submitted. Mr. Trull informed DHSS Deputy Administrator, David Lanigan, that the "measurements are not accurate" in the floor plan and request. Additionally, the floor plan did not accurately reflect additional walls inside the exam rooms. Furthermore, Mr. Trull was not familiar with RHS' plan regarding room locations, as identified in the request. Please find the below determinations regarding your request:

1. **Patient-Serving Corridors and Doors**

19 CSR 30-30.070(3)(B) & (C), states, *"(B) Corridors serving patients shall be at least six feet (6') wide; (C) All doors through which patients pass shall be at least forty-four inches (44") wide and of solid-core construction;"*

The RHS request indicates that patient-serving corridors are 4'7" wide and pass through doors are at least 32" wide and of hollow-core construction. The RHS request further asserts that the Springfield health center's current corridors and doors comply with the requirement at 19 CSR 30-30.070 (4)(B).

DHSS staff observed that the passageways at the facility are not adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit. The procedure room is constructed with barriers to maneuverability (inner walls and small spaces) not shown on the provided floor plan. As constructed, the layout and location of the existing doors into this

room do not open fully to allow for a wheelchair or a gurney to be easily moved out of the room in an emergency. In addition, the corridors serving patients and the door widths of the patient rooms other than the procedure room (noted as Exam Rooms #1, #2, and #3 on the floor plan provided to DHSS) are not of sufficient size to allow a stretcher to be promptly maneuvered in and a patient on a stretcher to be promptly maneuvered out of those rooms to a street-level exit. Only one exterior door meets the requirements of being 44" or wider.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(B) & (C). DHSS is willing to reconsider this request if RHS provides an adequate remediation plan that ensures prompt maneuverability of a patient on a stretcher into and out of the procedure room and other patient rooms in an emergency event.

2. **Construction Type**

19 CSR 30-30.070(3)(D) states, "*(D) One- (1-) story buildings shall be at least of Type II (111) protected noncombustible construction as described in Standard on Types of Building Construction 1979 published by the National Fire Protection Association;*"

The RHS request indicates that the Springfield facility is of "Type V (100) unprotected combustible construction." The RHS request further asserts that the Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the construction type of the facility is Type V (000), unprotected combustible construction. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility's construction is insufficient to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(D). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

3. **Fire Alarm**

19 CSR 30-30.070(3) (H) states, "*(H) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;*".

The RHS request indicates that the Springfield facility does not have manual fire alarm break stations at each exit. The RHS request further asserts that the Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the facility lacks the required alarm break stations near each exit, connected to a local audible alarm. The facility is currently protected by three ABC-fire extinguishers and spot-type smoke detectors located in most, but not all rooms. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility is insufficiently equipped with fire alarm break stations to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(H). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

4. **Scrub Station**

19 CSR 30-30.070(3) (L) states, "*(L) Scrub-up facilities shall be knee- or foot-operated and provided at the rate of one (1) per procedure room. Scrub-up facilities shall be located outside but immediately available to the procedure room;*"

The RHS request indicates that the Springfield facility does have a scrub station located inside the room identified as the procedure room.

DHSS staff confirmed that the facility has a sink in the procedure room that is not knee-or-foot operated, as required.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(L), provided the current sink is replaced with a knee or foot operated scrub station, as noted in the request and it is physically separated by a wall or partition from the patient and procedure equipment to prevent contamination while scrubbing for procedures.

5. **Procedure Room**

19 CSR 30-30.070(3) (M) states, "*(M) Procedure rooms shall have the following: 1. A minimum length and width of twelve feet (12'); 2. A minimum ceiling height of nine feet (9'); 3. A door with a minimum width of forty-four inches (44"); and 4. There shall be no windows in the room except there may be a fixed-view window in the wall between the procedure room and the adjacent corridor;*"

The RHS request indicates that the Springfield facility's procedure room was 12'6" by 11'6", the ceiling height is 7'9 and the door width is 36." The RHS request further asserts that the dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

RHS representative, Mr. Trull, identified Exam Room #4 as the procedure room. The measurements and configuration of Exam Room #4 differed from the floor plan provided to DHSS. According to the floor plan, the measurements of the room are "16-9 ½" by "13'". Further, the floor plan nor the measurements in the waiver request account for interior walls that break up the room, limiting mobility. Mr. Trull, acknowledged the measurements provided by RHS were "not accurate." DHSS staff observed that the procedure table is located in an alcove that is 7' in width and separated from an adjacent open area with a 4'6" wing-wall. The identified procedure room is insufficient in size and configuration to allow medical staff to move freely in the event of an emergency (see attached photos).

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(M)(1) and (3). DHSS approves the request for deviation from 19 CSR 30-30.070(3)(M)(2). DHSS is willing to reconsider the denied aspects of this request if RHS provides an adequate remediation plan that ensures prompt

maneuverability of a patient on a stretcher into and out of the procedure room in the event of an emergency.

6. **Recovery Room**

19 CSR 30-30.070 (3) (N) states, "*(N) The recovery room shall be separated from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner;*"

The RHS request indicates that the Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner.

RHS representative, Mr. Trull, could not identify which room would be utilized as the recovery room. Mr. Trull stated he was "not sure of the plan" and didn't think RHS had decided where the room would be located. Without knowing which room would be the recovery room, DHSS cannot determine whether a deviation is warranted.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(N). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room.

7. **HVAC**

19 CSR 30-30.070 (3)(O) states, "*(O) The procedure room and recovery room shall be provided with a minimum of six (6) air changes per hour. Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rating;*"

The RHS request indicates that the Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. Mr. Trull was unable to provide documentation of the facility's current air exchange rate or current efficiency rating for evaluation. Further, Mr. Trull could not identify the location of the recovery room, which restricts DHSS's ability to determine whether a deviation is warranted.

Lastly, the fact that DHSS determined in 1987 that the requirements for then-existing abortion facilities need not include a minimum number of air changes per hour or a filter with a minimum efficiency rating does not mean—as suggested in the RHS request—that requiring these things for facilities constructed after the rule was promulgated in 1987 has no effect on improving patient health or safety. This provision of this rule, like others discussed in this letter, was promulgated in 1987 under DHSS's authority in section 197.225 RSMo to assure quality patient care through standards that insure the health, safety, and comfort of patients. Requirements of minimum air changes per hour are also required by DHSS for ambulatory surgical centers generally and birthing centers. Any deviations from this rule, as with others, would need to be based on a legitimate and persuasive reason provided by the requester. Here, the only reason provided for a deviation is that DHSS does not require in the rule minimum air changes and filter efficiency ratings for then-existing abortion facilities in 1987. This reason is not sufficient. The reported cost (as alleged in the request) of $2.26 million to comply with the rule in total, moreover, provides no indication how much of that total would be attributable to these particular

requirements. And as noted above, Mr. Trull could not provide documentation showing the current ventilation capabilities. Under these circumstances, DHSS cannot reasonably grant a deviation from a rule designed to insure the health, safety, and comfort of patients.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(O). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room and provides adequate information that allows DHSS to meaningfully assess the Springfield facility's current air exchange rate and efficiency rating.

8. **Personnel-Change Room**

19 CSR 30-30.070 (3) (P) states, "*(P) Personnel change rooms shall be provided for each sex and located convenient to the procedure room. Each change room shall be equipped with a toilet and lavatory;*"

The RHS request indicates that the Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory.
RHS representative, Mr. Trull, identified a restroom, in close proximity to the procedure room as a personnel-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(P).

9. **Ceiling-Mounted Surgical Light**

19 CSR 30-30.070 (3) (R) states, "*(R) The procedure room shall be equipped with a ceiling-mounted surgical light, operating table or a conventional gynecological examining table with accessories, closed cabinets for equipment, and sufficient tables to hold an emergency tray and other necessary equipment;*"

The RHS request indicates that the Springfield facility will equip the procedure room with a wall-mounted surgical light, which would be better angled for the procedures they provide.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(R) based on the current configuration and available space within the identified procedure room, which is limited by an interior wall directly to the left of the room entrance. This wall does not allow sufficient space in the room for mounting the surgical light on the wall. DHSS is willing to reconsider this request if modifications are made to the room that allow sufficient space to mount the surgical light on the wall.

10. **Sterilization Room**

19 CSR 30-30.070 (3) (V) states, "*(V) The sterilizing room shall be equipped with a steam sterilizer, counter and sink, and storage space for clean supplies. Air pressure in this room shall be positive in relation to adjacent areas;*"

The RHS request indicates that the air pressure in the Springfield facility's sterilizing room is not positive in relation to the adjacent areas. Mr. Trull was unable to identify the location of the sterilization room or provide documentation of the room's current air pressure for evaluation. As with the recovery

room, this restricts DHSS's ability to determine whether a deviation is warranted. And for similar reasons set forth above with respect to the request for deviation from the ventilation requirements, the mere fact that DHSS did not express this as a requirement for abortion facilities in existence when the rule was promulgated in 1987 is not sufficient reason to justify deviation from the rule.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(V). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the sterilizing room and provides adequate information that allows DHSS to meaningfully assess the sterilizing room's air pressure in relation to adjacent areas.

11. **Patient-Change Rooms**

19 CSR 30-30.070 (3) (Y) states, "*(Y) At least two (2) patient change rooms with secure storage for personal effects shall be provided;*"

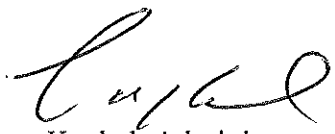
The RHS request indicates that the Springfield facility has one patient-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(Y) under the condition that patient belongings travel with the patient in a secure container, it uses only one (1) procedure room and does not use the procedure room as the change room.

The deviation approvals contained in this correspondence may be revoked any time DHSS determines: (1) that patient care or safety may be compromised, (2) that the facility is not in full compliance with applicable rules, or (3) the facility fails to adhere to all conditions of the approved deviations.

Thank you again for your willingness to coordinate an on-site walk-through of the Springfield facility. Should you have further questions regarding this letter, please contact David Lanigan at David.Lanigan@health.mo.gov or by calling (573) 526-1864.

Sincerely,



William Koebel, Administrator
Section for Health Standards and Licensure
Division of Regulation and Licensure
Department of Health and Senior Services

Americans United for Life

Planned Parenthood
Care. No matter what.

Planned Parenthood of the St. Louis Region and Southwest Missouri

Administrative Office
4251 Forest Park Avenue
St. Louis, MO 63108

p. 314.531.7526 | f. 314.531.9731
www.plannedparenthood.org/stlouis

February 1, 2019

Via email to: William.Koebel@health.mo.gov

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: *Request for Deviation*

Dear Mr. Koebel:

Pursuant 19 CSR 30-30.070(2), I write to request deviations/waivers of certain physical standards for Reproductive Health Services of Planned Parenthood of the St. Louis Region's (RHS) health center in Springfield.

The physical facility restrictions in 19 CSR 30-30.070 prevent us from providing surgical abortion in our Springfield health center. RHS remains committed to providing abortion services to the women of Southwest Missouri, and therefore by this letter seeks waivers of those requirements it cannot meet. We request the Department "exercise[] the Waiver Provision" "with sufficient flexibility" and reasonableness. *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, 903 F.3d 750, 756–57 (8th Cir. 2018).

Abortion Safety

As you know, RHS has safely provided abortion services in Missouri for many years. The physical facility restrictions are medically unnecessary and do not improve the health and safety of our patients seeking abortion care. Indeed, the Department has recognized as much when it waived a number of medically unnecessary restrictions in a 2010 settlement with the Columbia health center.

Abortion is one of the safest medical procedures in the United States. As the National Academies of Sciences, Engineering, and Medicine—which recently conducted a systematic review of the safety and quality of care of abortion in the United States—found, abortion in the United States is safe. In particular, first-trimester aspiration

abortion, which we seek to provide in the Springfield health center, "is a minimally invasive and commonly used gynecological procedure," including "in cases of early pregnancy loss (miscarriage)."[1] Aspiration abortion is effective at terminating an early pregnancy in more than 99% of those provided, and complications from first-trimester aspiration abortion occur in approximately 1.26% of patients—and serious complication in less than 0.02%.[2] Aspiration abortion may require no or only minimal sedation.

As the National Academies observed, "[a]spiration abortions are performed safely in office and clinic settings."[3] Abortion-specific regulations—such as the physical facility restrictions in 19 CSR 30-30.070—serve only to "diminish" the quality of care women receive by "limit[ing] the number of available providers."[4]

Requested Waivers

Against the backdrop of abortion's demonstrated safety, and given that the current facility is sufficient to protect patient health and safety, we make the following waiver requests. We note at the outset that we are committed to working with the Department on these issues so that we can begin providing abortion services to our patients at the Springfield health center. We also note that the Springfield facility meets many of the requirements in 19 CSR § 30-30.070(4), which applies to facilities existing at the time the regulation was adopted, and therefore, demonstrates the Department's understanding that these provisions are sufficient to protect patient health and safety.

1. **Patient-Serving Corridors and Doors**

Subsections 30-30.70(3)(B) & (C) require patient-serving corridors be at least 6' wide and doors through which patients pass be at least 44" wide and of solid-core construction. Patient-serving corridors at the Springfield center are 4'7" wide and doors through which patients pass are at least 32" wide and of hollow-core construction.

The Springfield health center's current system of corridors and doors adequately protect patient health and safety by allowing a patient to be moved by stretcher from any point in the facility to the outside via the main entrance. Indeed, the Springfield health center's current corridors and doors comply with the requirement at 19 CSR § 30-30.070(4)(B) that the system of corridors and passageways be "adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit." We also note that the Department agreed to a similar corridor dimension for the Columbia health center in a 2010 settlement agreement.

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[1] Nat'l Acad. of Sciences, Engineering & Medicine, The Safety and Quality of Abortion Care in the United States 2-12 (2018).
[2] *Id.* at 2-12 to 2-13 (citing Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 124 Obstetrics & Gynecology 175 (2015)).
[3] *Id.* at S-8.
[4] *Id.* at S-10.

2. Construction Type

Subsection 30-30.70(3)(D) requires one-story buildings be at least of Type II (111) protected noncombustible construction as described in *Standard on Types of Building Construction* 1979 published by the National Fire Protection Association. The Springfield facility is of Type V (100) unprotected combustible construction.

The Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The higher fire-safety rating is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

3. Fire Alarm

Subsection 30-30.70(3)(H) requires a manual fire alarm break station be located near each exit and connected to a local audible alarm that can be heard throughout the facility. The Springfield health center does not have manual fire alarm break stations at each exit.

The Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The requirement is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

4. Scrub Station

Subsection 30-30.70(3)(L) requires a scrub-up facility be knee- or foot-operated and be located outside the procedure room. The Springfield health center has a scrub station located inside the procedure room. The requirement that the scrub station be located outside the procedure room does not protect patient health or safety. The Springfield

center complies with the requirement in 19 CSR § 30-30.070(4)(F) that the scrub-up facility be located convenient to the procedure room.[5]

5. Procedure Room

Subsection 30-30.70(3)(M) requires that all procedure rooms be a minimum of 12' length and width, 9' ceiling height, and doors with a width of at least 44". The Springfield facility's procedure room's dimensions are 12'6" by 11'6", ceiling height of 7'9", and door width of 36".

The dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

Further, the Springfield health center's existing procedure room meets the requirement at 19 CSR § 30-30.070(4)(E) that it be "adequately equipped, supplied, and staffed to safely perform abortions," which the Department has determined is sufficient to protect patient health and safety; this requirement does not specify minimum dimensions. The room is of sufficient size to fit a gynecologic examining table with accessories, a closed cabinet for equipment, and tables to hold an emergency tray and other necessary equipment.

Requiring compliance with the nine-foot ceiling height would not advance patient health and safety, because such ceiling height requirements generally are intended to facilitate installation of a ceiling-mounted surgical light. These lights would not be appropriate to the procedures done at the Springfield health center, for the reasons given below under request no. 9. Requiring compliance with the 44" door width would not advance patient health and safety at the Springfield health center because, as discussed above under request no. 1, the current system of corridors and doors allows rapid patient evacuation in the event of an emergency. Finally, we note that the Department agreed to similar dimensions of 12' length, 9' 0.5" width, and 8' 6"' height for the Columbia health center in a 2010 settlement agreement.

6. Recovery Room

Subsection 30-30.70(3)(N) requires the recovery room be of sufficient size for four recovery recliners or beds with 3' of clear space on both sides and at the foot of each recliner or bed.

The Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner. We do not anticipate scheduling—and will agree to not schedule—more patients than the recovery room can accommodate. We note that the Department recently approved a deviation from this requirement for the Columbia facility to permit three recliners.

[5] We acknowledge our current scrub sink is not knee- or foot-operated. We will replace the current sink with a knee- or foot-operated if the Department approves this waiver.

7. HVAC

Subsection 30-30.70(3)(O) requires the procedure and recovery rooms be provided with a minimum of six air changes per hour and filtered through a filter with at least a twenty-five percent (25%) efficiency rating. The Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. This requirement is not necessary for patient health or safety, particularly since surgical abortion does not require a sterile operating room environment, as demonstrated by its omission in 19 CSR § 30-30.070(4).

8. Personnel-Change Room

Subsection 30-30.70(3)(P) requires personnel-change rooms be provided for each sex, located convenient to the procedure room, and equipped with a toilet and lavatory. The Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory. We note that the Department agreed to a similar deviation for the Columbia health center in a 2010 settlement agreement.

9. Ceiling-Mounted Surgical Light

Subsection 30-30.70(3)(R) requires the the procedure room be equipped with a ceiling-mounted light. The Springfield facility's procedure room would be equipped with a walled-mounted surgical light, which is better angled for the procedures that would be provided. We note that the Department agreed to similar deviation for the Columbia health center in a 2010 settlement agreement.

10. Sterilizing Room

Subsection 30-30.70(3)(V) requires that air pressure in the sterilizing room be positive in relation to adjacent areas. The air pressure in the Springfield health center's sterilizing room is not positive in relation to adjacent areas. This requirement is not necessary for patient health or safety, as demonstrated by its omission in 19 CSR § 30-30.070(4).

11. Patient-Change Rooms

Subsection 30-30.70(3)(Y) requires there be at least two patient-change rooms with secure storage for personal effects. The Springfield facility has one patient-change room. We note that the Department agreed to deviation for the Columbia health center in a 2010 settlement agreement such that there could be one patient-change room if the patient traveled with her belongings in a secure container. We will agree to do the same or provide the patient with secure storage in the patient-change room.

Burdens

Complying with the physical facility requirements in 19 CSR 30-30.070 at our Springfield facility would be prohibitively expensive and burdensome. A recent survey of the facility by a licensed architect found that it would cost $2.26 million to remodel the Springfield health center to meet the requirements in 19 CSR 30-30.070, which is approximately the same amount to construct a new facility. Construction would take

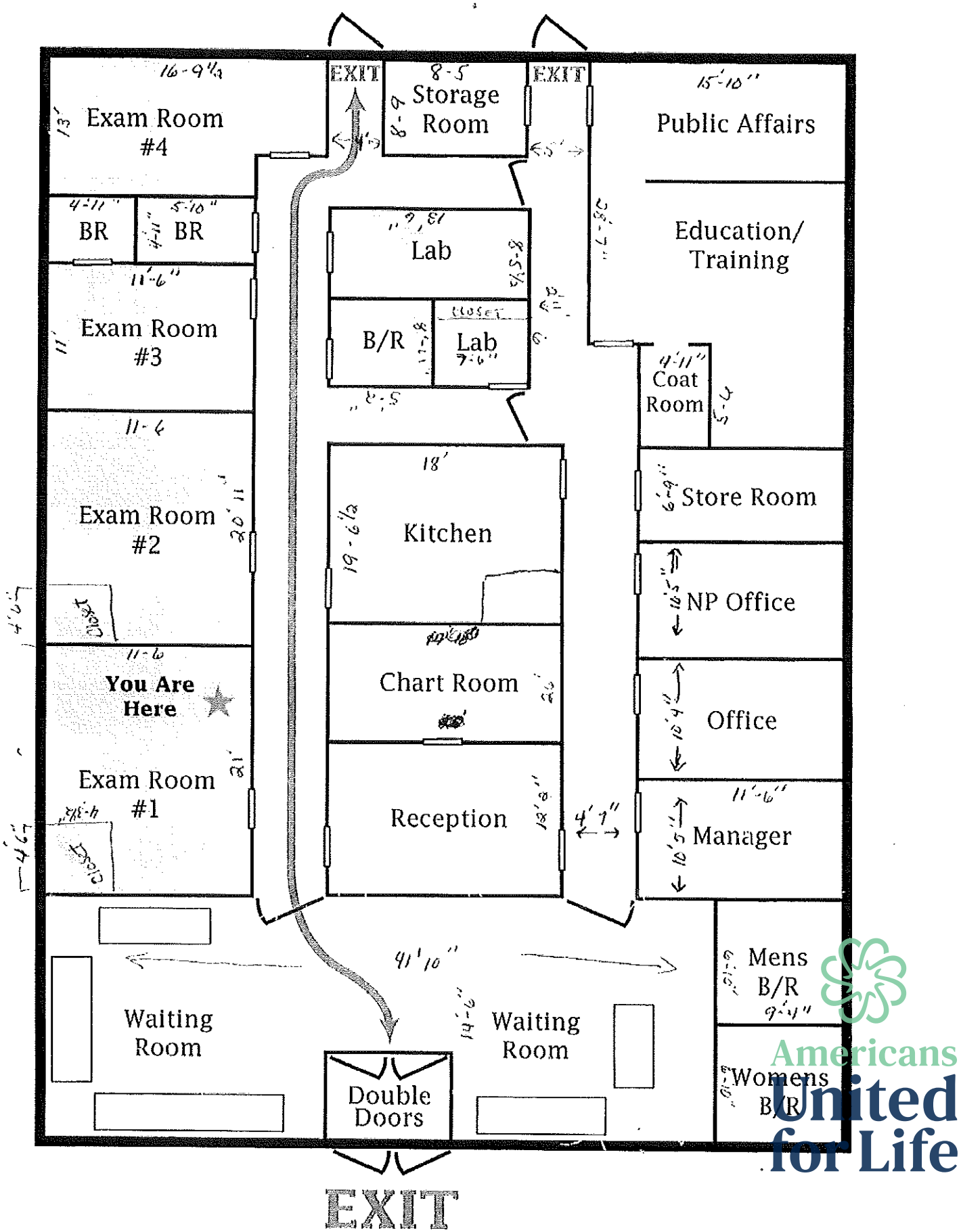
approximately eight months to complete and include complete removal and installation of the roof and exterior walls. As a result, such construction would completely disrupt the critical health services currently provided there, including family planning services that help prevent unplanned pregnancies.

Please let me know if you have any questions regarding this request. I look forward to hearing your prompt response.

Sincerely,

Janice Thomas
Vice President of Patient Services & Research

Americans United for Life



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Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

April 17, 2019

Cathy Williams, Interim President & CEO
Reproductive Health Services of Planned Parenthood
425 Forest Park Avenue
St. Louis, MO 63108

Re: Request for Deviation (RHS Health Center – Springfield, MO)

Dear Ms. Williams:

On February 1, 2019, Reproductive Health Services (RHS) submitted a Request for Deviations from some requirements of 19 CSR 30-30.070, for RHS' health center in Springfield, Missouri (attached).

The Department requested that RHS provide a code review sheet and architectural plans, as the request lacked sufficient information for DHSS to reasonably approve or deny the requests. In response, on February 8, 2019, RHS provided a facility floor plan (attached). The additionally provided information remained insufficient to make a determination. A mutually agreeable onsite walk-through was arranged for March 5, 2019, in order to gather sufficient information to respond to the submitted request.

On March 5, 2019, DHSS staff conducted a walk-through of the Springfield facility. RHS facilities manager, Chris Trull, represented RHS. The walk-through identified additional concerns related to the initial request submitted. Mr. Trull informed DHSS Deputy Administrator, David Lanigan, that the "measurements are not accurate" in the floor plan and request. Additionally, the floor plan did not accurately reflect additional walls inside the exam rooms. Furthermore, Mr. Trull was not familiar with RHS' plan regarding room locations, as identified in the request. Please find the below determinations regarding your request:

1. **Patient-Serving Corridors and Doors**

19 CSR 30-30.070(3)(B) & (C), states, *"(B) Corridors serving patients shall be at least six feet (6') wide; (C) All doors through which patients pass shall be at least forty-four inches (44") wide and of solid-core construction;"*

The RHS request indicates that patient-serving corridors are 4'7" wide and pass through doors are at least 32" wide and of hollow-core construction. The RHS request further asserts that the Springfield health center's current corridors and doors comply with the requirement at 19 CSR 30-30.070 (4)(B).

DHSS staff observed that the passageways at the facility are not adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit. The procedure room is constructed with barriers to maneuverability (inner walls and small spaces) not shown on the provided floor plan. As constructed, the layout and location of the existing doors into this

room do not open fully to allow for a wheelchair or a gurney to be easily moved out of the room in an emergency. In addition, the corridors serving patients and the door widths of the patient rooms other than the procedure room (noted as Exam Rooms #1, #2, and #3 on the floor plan provided to DHSS) are not of sufficient size to allow a stretcher to be promptly maneuvered in and a patient on a stretcher to be promptly maneuvered out of those rooms to a street-level exit. Only one exterior door meets the requirements of being 44" or wider.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(B) & (C). DHSS is willing to reconsider this request if RHS provides an adequate remediation plan that ensures prompt maneuverability of a patient on a stretcher into and out of the procedure room and other patient rooms in an emergency event.

2. **Construction Type**

19 CSR 30-30.070(3)(D) states, "*(D) One- (1-) story buildings shall be at least of Type II (111) protected noncombustible construction as described in Standard on Types of Building Construction 1979 published by the National Fire Protection Association;*"

The RHS request indicates that the Springfield facility is of "Type V (100) unprotected combustible construction." The RHS request further asserts that the Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the construction type of the facility is Type V (000), unprotected combustible construction. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility's construction is insufficient to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(D). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

3. **Fire Alarm**

19 CSR 30-30.070(3) (H) states, "*(H) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;*".

The RHS request indicates that the Springfield facility does not have manual fire alarm break stations at each exit. The RHS request further asserts that the Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the facility lacks the required alarm break stations near each exit, connected to a local audible alarm. The facility is currently protected by three ABC-fire extinguishers and spot-type smoke detectors located in most, but not all rooms. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility is insufficiently equipped with fire alarm break stations to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(H). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

4. **Scrub Station**

19 CSR 30-30.070(3) (L) states, "*(L) Scrub-up facilities shall be knee- or foot-operated and provided at the rate of one (1) per procedure room. Scrub-up facilities shall be located outside but immediately available to the procedure room;*"

The RHS request indicates that the Springfield facility does have a scrub station located inside the room identified as the procedure room.

DHSS staff confirmed that the facility has a sink in the procedure room that is not knee-or-foot operated, as required.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(L), provided the current sink is replaced with a knee or foot operated scrub station, as noted in the request and it is physically separated by a wall or partition from the patient and procedure equipment to prevent contamination while scrubbing for procedures.

5. **Procedure Room**

19 CSR 30-30.070(3) (M) states, "*(M) Procedure rooms shall have the following: 1. A minimum length and width of twelve feet (12'); 2. A minimum ceiling height of nine feet (9'); 3. A door with a minimum width of forty-four inches (44"); and 4. There shall be no windows in the room except there may be a fixed-view window in the wall between the procedure room and the adjacent corridor;*"

The RHS request indicates that the Springfield facility's procedure room was 12'6" by 11'6", the ceiling height is 7'9 and the door width is 36." The RHS request further asserts that the dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

RHS representative, Mr. Trull, identified Exam Room #4 as the procedure room. The measurements and configuration of Exam Room #4 differed from the floor plan provided to DHSS. According to the floor plan, the measurements of the room are "16-9 ½" by "13'". Further, the floor plan nor the measurements in the waiver request account for interior walls that break up the room, limiting mobility. Mr. Trull, acknowledged the measurements provided by RHS were "not accurate." DHSS staff observed that the procedure table is located in an alcove that is 7' in width and separated from an adjacent open area with a 4'6" wing-wall. The identified procedure room is insufficient in size and configuration to allow medical staff to move freely in the event of an emergency (see attached photos).

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(M)(1) and (3). DHSS approves the request for deviation from 19 CSR 30-30.070(3)(M)(2). DHSS is willing to reconsider the denied aspects of this request if RHS provides an adequate remediation plan that ensures prompt

maneuverability of a patient on a stretcher into and out of the procedure room in the event of an emergency.

6. **Recovery Room**

19 CSR 30-30.070 (3) (N) states, "*(N) The recovery room shall be separated from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner;*"

The RHS request indicates that the Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner.

RHS representative, Mr. Trull, could not identify which room would be utilized as the recovery room. Mr. Trull stated he was "not sure of the plan" and didn't think RHS had decided where the room would be located. Without knowing which room would be the recovery room, DHSS cannot determine whether a deviation is warranted.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(N). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room.

7. **HVAC**

19 CSR 30-30.070 (3)(O) states, "*(O) The procedure room and recovery room shall be provided with a minimum of six (6) air changes per hour. Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rating;*"

The RHS request indicates that the Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. Mr. Trull was unable to provide documentation of the facility's current air exchange rate or current efficiency rating for evaluation. Further, Mr. Trull could not identify the location of the recovery room, which restricts DHSS's ability to determine whether a deviation is warranted.

Lastly, the fact that DHSS determined in 1987 that the requirements for then-existing abortion facilities need not include a minimum number of air changes per hour or a filter with a minimum efficiency rating does not mean—as suggested in the RHS request—that requiring these things for facilities constructed after the rule was promulgated in 1987 has no effect on improving patient health or safety. This provision of this rule, like others discussed in this letter, was promulgated in 1987 under DHSS's authority in section 197.225 RSMo to assure quality patient care through standards that insure the health, safety, and comfort of patients. Requirements of minimum air changes per hour are also required by DHSS for ambulatory surgical centers generally and birthing centers. Any deviations from this rule, as with others, would need to be based on a legitimate and persuasive reason provided by the requester. Here, the only reason provided for a deviation is that DHSS does not require in the rule minimum air changes and filter efficiency ratings for then-existing abortion facilities in 1987. This reason is not sufficient. The reported cost (as alleged in the request) of $2.26 million to comply with the rule in total, moreover, provides no indication how much of that total would be attributable to these particular

requirements. And as noted above, Mr. Trull could not provide documentation showing the current ventilation capabilities. Under these circumstances, DHSS cannot reasonably grant a deviation from a rule designed to insure the health, safety, and comfort of patients.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(O). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room and provides adequate information that allows DHSS to meaningfully assess the Springfield facility's current air exchange rate and efficiency rating.

8. **Personnel-Change Room**

19 CSR 30-30.070 (3) (P) states, "*(P) Personnel change rooms shall be provided for each sex and located convenient to the procedure room. Each change room shall be equipped with a toilet and lavatory;*"

The RHS request indicates that the Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory.
RHS representative, Mr. Trull, identified a restroom, in close proximity to the procedure room as a personnel-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(P).

9. **Ceiling-Mounted Surgical Light**

19 CSR 30-30.070 (3) (R) states, "*(R) The procedure room shall be equipped with a ceiling-mounted surgical light, operating table or a conventional gynecological examining table with accessories, closed cabinets for equipment, and sufficient tables to hold an emergency tray and other necessary equipment;*"

The RHS request indicates that the Springfield facility will equip the procedure room with a wall-mounted surgical light, which would be better angled for the procedures they provide.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(R) based on the current configuration and available space within the identified procedure room, which is limited by an interior wall directly to the left of the room entrance. This wall does not allow sufficient space in the room for mounting the surgical light on the wall. DHSS is willing to reconsider this request if modifications are made to the room that allow sufficient space to mount the surgical light on the wall.

10. **Sterilization Room**

19 CSR 30-30.070 (3) (V) states, "*(V) The sterilizing room shall be equipped with a steam sterilizer, counter and sink, and storage space for clean supplies. Air pressure in this room shall be positive in relation to adjacent areas;*"

The RHS request indicates that the air pressure in the Springfield facility's sterilizing room is not positive in relation to the adjacent areas. Mr. Trull was unable to identify the location of the sterilization room or provide documentation of the room's current air pressure for evaluation. As with the recovery

room, this restricts DHSS's ability to determine whether a deviation is warranted. And for similar reasons set forth above with respect to the request for deviation from the ventilation requirements, the mere fact that DHSS did not express this as a requirement for abortion facilities in existence when the rule was promulgated in 1987 is not sufficient reason to justify deviation from the rule.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(V). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the sterilizing room and provides adequate information that allows DHSS to meaningfully assess the sterilizing room's air pressure in relation to adjacent areas.

11. **Patient-Change Rooms**

19 CSR 30-30.070 (3) (Y) states, "*(Y) At least two (2) patient change rooms with secure storage for personal effects shall be provided;*"

The RHS request indicates that the Springfield facility has one patient-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(Y) under the condition that patient belongings travel with the patient in a secure container, it uses only one (1) procedure room and does not use the procedure room as the change room.

The deviation approvals contained in this correspondence may be revoked any time DHSS determines: (1) that patient care or safety may be compromised, (2) that the facility is not in full compliance with applicable rules, or (3) the facility fails to adhere to all conditions of the approved deviations.

Thank you again for your willingness to coordinate an on-site walk-through of the Springfield facility. Should you have further questions regarding this letter, please contact David Lanigan at David.Lanigan@health.mo.gov or by calling (573) 526-1864.

Sincerely,

William Koebel, Administrator
Section for Health Standards and Licensure
Division of Regulation and Licensure
Department of Health and Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired: 1-800-735-2466 VOICE: 1-866-735-2460

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

March 29, 2018

Janice Thomas
VP of Patient Services & Research
Reproductive Health Services of Planned Parenthood
4251 Forest Park Avenue
St. Louis, MO 63108

Via email to Janice.Thomas@ppslr.org

Re: Proposed complication plan for Springfield, Missouri facility

Dear Ms. Thomas:

The proposed complication plan submitted by Reproductive Health Services of Planned Parenthood for the Springfield facility on January 8, 2018, does not meet the requirements of Section 188.021, RSMo, and 19 CSR 30-30.061 in that:

The plan states that Dr. Grebe, a board-certified OB/GYN, will provide medical abortions in Springfield and treat the complications whenever possible. Whenever not possible, the plan states that either Dr. David Eisenberg or Dr. Orrin Moore respectively will personally treat complications at the Reproductive Health Services (RHS) facility in St. Louis or at a Comprehensive Health facility in Overland Park, Kansas. Dr. Eisenberg and the RHS facility are located over three hours driving time from the Springfield facility. Dr. Moore and the Overland Park facility are located over two-and-a-half hours driving time from the Springfield facility. As a result, neither Dr. Moore nor Dr. Eisenberg will be available to personally treat all complications in Dr. Grebe's absence, and patients who are not experiencing immediately life-threatening complications will be referred to the emergency room.

Additionally, the proposed plan fails to recognize the importance of the physician-patient relationship by providing for continuity of care and ensuring communication among the physician who induced the abortion and all subsequent health care providers involved in treating the patient's complication.

Because the facility's proposed plan does not meet the requirements of Section 188.021, RSMo, and 19 CSR 30-30.061, the Department cannot approve the plan. Accordingly, the Department cannot issue the facility a license until an approved plan is in place (and all other deficiencies have been corrected).
If the facility wishes to submit a new or revised plan, please send it to the Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102, or by email to John.Langston@health.mo.gov by April 15, 2018.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

Americans United for Life

ECU Recommendations

1. **Patient-Serving Corridors and Doors**

   19 CSR 30-30.070

   (B) Corridors service patients shall be at least six feet (6') wide;

   (C) All doors through which patients pass shall be at least forty-four inches (44") wide and of solid-core construction.

   The floor plan layout submitted was misleading and incorrect. Although the overall layout of the corridor system and surrounding rooms is shown correctly, many interior walls within the exam rooms were excluded from the floor plans. The walls that were not indicated in the plan are critical in determining the layout of the clinic space for emergency egress and proper dimensions. In addition, none of the doors, except the exterior exit doors and doors leading from the waiting room to the clinic, were shown to include the direction of door swing. None of the doors shown on the floor plan layout indicated the size of the doors.

   Corridors:

   19 CSR 30-30.070(B) Corridors service patients shall be at least six feet (6') wide;

   The corridors that would be considered part of the clinic/patient side of the facility are 4'-7" wide and then become 4'-0" wide at the exit corridor at the back of the building. While the waiver request noted that "the Department agreed on a similar corridor dimension for CoMo." This statement is not accurate as "similar" does not imply sameness in this particular comparison. CoMo had a minimum of 5'-1" wide corridors with one corridor being 5'-7" wide throughout the facility.

   Doors:

   19 CSR 30-30.070 (C) All doors through which patients pass shall be at least forty-four inches (44") wide and of solid-core construction.

   CoMo was not required to revise the door widths in the facility from the existing 36" wide doors (typically 33.5" opening width at 90 degrees) to 44" wide doors per the Regulations. However, the doors to the procedure and recovery rooms were revised to "wing next to the wall and out of the way of the gurney." The room noted as Exam Room #4 on the floor plan layout provided to DHSS is to be used to the future Procedure Room. As constructed, the layout and location of the existing doors into this room do not allow to be opened fully to allow for a wheelchair or a gurney to be easily moved out of the room in an emergency. The facility did not provide a location of the Recovery room so DHSS was unable to assess the viability of emergency egress in this room. The doors from the waiting room to the corridor is 42" wide with the exterior exit door being 36" wide.

2. **Construction Type**

   19 CSR 30-30.070(D) One (1)-story buildings shall be at least of Type II (111) protected noncombustible construction...or shall be protected throughout by an approved automatic sprinkler system"

   The construction type of SGF is Type V (000). Because the Regulations require a single story facility to be Type II (111) construction, this building would need to be equipped with an NFPA

13 compliant sprinkler system as an alternative, as stated in the regulations. The Columbia health center was required to make the same revisions to their facility.

3. **Fire Alarm**

   19 CSR 30-30.070(H) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;

   SGF is currently protected by three ABC-fire extinguishers and spot-type smoke detectors located in most, but not all rooms. Manual fire alarm break stations are not installed at the exits or anywhere in the building. At a minimum, these fire alarm break stations shall be installed at each exit. In addition, a local audible alarm shall be connected to these stations that can be heard throughout the facility.

4. **Scrub Station**

   19 CSR 30-30.070 (L) Scrub-up facilities shall be knee- or foot-operated and provided at the rate of one (1) per procedure room. Scrub-up facilities shall be located outside but immediately available to the procedure room.

   The scrub station located inside the procedure room is acceptable if a knee- or foot-operated device is used and the scrub station is physically separated by a wall or partition from the patient and procedure equipment to prevent contamination while scrubbing for procedures.

5. **Procedure Room**

   19 CSR 30-30.070(M) Procedure room shall have the following:

   1. *A minimum length and width of twelve feet (12');*
   2. *A minimum ceiling height of nine feet (9');*
   3. *A door with a minimum width of forty-four inches (44")*

   During an onsite visit, DHSS was advised that the existing Exam Room #4 was to be intended for use as the Procedure Room. Based on dimensions taken on site, the floor plan layout provided to DHSS does not include several walls and a door. If a patient were to require emergency resuscitation or other emergency rescue methods, this room does not provide adequate area to allow personnel to perform emergency rescue procedures in a safe manner. In addition, the layout of the existing walls and doors make it impossible to easily wheel a gurney or a wheelchair out of the room. In order for this room to be used as a Procedure Room, it is suggested that several walls and the interior door is removed to create more usable space. In addition, based on earlier comments regarding the scrub station, this area shall be isolated and apart from the patient area of the room. Prior to approval, a correct layout of the room showing the dimensions, cabinet locations, sink location, door location and door size.

6. **Recovery Room**

   19 CSR 30-30.070(2)

   (N) The recovery room shall be separated from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the food of each recovery bed or recliner.

   (T) There shall be one (1) electrical outlet in the recovery room for the emergency light and at least one (1) duplex outlet for each two (2) recover beds or recliners.

   During an onsite visit, a staff member was unable to advise the location of this room. More information will need to be submitted prior to approval for this room including exact

dimensions, location of proposed recliners and clear space dimensions, and the location of electrical outlets as required.

7. **HVAC**

   19 CSR 30-30.070(O) The procedure room and recovery room shall be provided with a minimum of six (6) air changes per hour. Air supplied to all areas shall be filtered through a filer with at least a twenty-five person (25%) efficiency rating.

   While DHSS recognizes that the existing HVAC may not be adequate to meet the Regulations, additional information about the existing HVAC system installed shall be submitted including the existing number of air changes per hour for these rooms.

   In addition, there are several areas in question that will need to be addressed prior to potential licensing:

   a. **Soiled/Decontamination Room** – Similar to CoMo, SGF shall provide a separate soiled/decontamination room with a constant running exhaust. The existing soiled/decontamination room had an exhaust fan that did not work. In addition, this room was open to the corridor. If this room is to be used, a self-closing door shall be added and the exhaust fan shall be repaired and provide constant running exhaust.
   b. **Patient Toilet Facilities** - The patient toilet facilities are currently provided with an exhaust fan that runs when the light switch is turned to the on position. These fans shall also be equipped with a constant running exhaust.

8. **Personnel-Change Room**

   19 CSR 30-30.070 (P) Personnel change rooms shall be provided for each sex and located convenient to the procedure room. Each change room shall be equipped with a toilet and lavatory

   During the onsite visit, it was unclear to DHSS which are was to be used for the Personnel-Change Room. While it may be acceptable to potentially provide one gender neutral personnel change room that is convenient to the procedure room and equipped with a toilet and lavatory, more information will be required to be submitted on the location of this area including dimensions of the room and dimensions of the toilet room.

9. **Ceiling-Mounted Surgical Light**

   19 CSR 30-30.070(R) The procedure room shall be equipped with a ceiling-mounted surgical light, operating table or a conventional gynecological examining table with accessories, closed cabinets for equipment and sufficient tables to hold an emergency tray and other necessary equipment

   Because the proposed procedure room floor plan layout submitted was incorrect, more information shall be submitted and reviewed prior to approval to this waiver. The location of this light shall be shown on the resubmitted floor plan layout of the proposed procedure room.

10. **Sterilizing Room**

    19 CSR 30-30.070(2)(V) The sterilizing room shall be equipped with a steam sterilizer, counter and sink, and storage room for clean supplies. Air pressure in this room shall be positive in relation to adjacent areas.

    Similar to CoMo, the Springfield health center shall provide a sterilization room with positive air pressure in relation to adjacent areas. While the waiver request notes "this requirement is not

necessary for patient health or safety, as demonstrated by its omission in 19 CSR 30-30.070(4), no information can be found on this reference after the 1998 publication of the Regulations.

11. **Patient-Change Rooms**

    19 CSR 30-30.070(Y) At least two (2) patient change rooms with secure storage for personal effects shall be provided

    In the floor plan layout provided to DHSS, this patient-change room was not identified, nor did the staff member on site have any information of the location of this room. Additional information shall be submitted to DHSS providing the location of this room, dimensions of the room and other requirements. Once this information has been submitted and reviewed, this waiver may be granted as stated above.

12. Additional Requirements

    As noted on the onsite visit, the existing ceiling tile in the clinical area is not of a type that is smooth or easily cleanable. Many existing tiles were dirty and covered with dust particles. Similar to the CoMo, SGF shall install ceiling tile in the clinical area that is smooth and easily cleanable.

Burdens

I believe that the financial burden listed in this paragraph are misleading. While it may cost $2.26 million to remodel the existing facility to meet the State Regulations in their entirety, a typical cost estimate provided by a licensed professional should provide a break-down of the items listed. It would be in the best interest of SGF to model their renovations based on past approvals with CoMo. A more appropriate cost may be issued that not only is much lower, but still protects the patients and staff of the facility in the "unlikely event of a fire."

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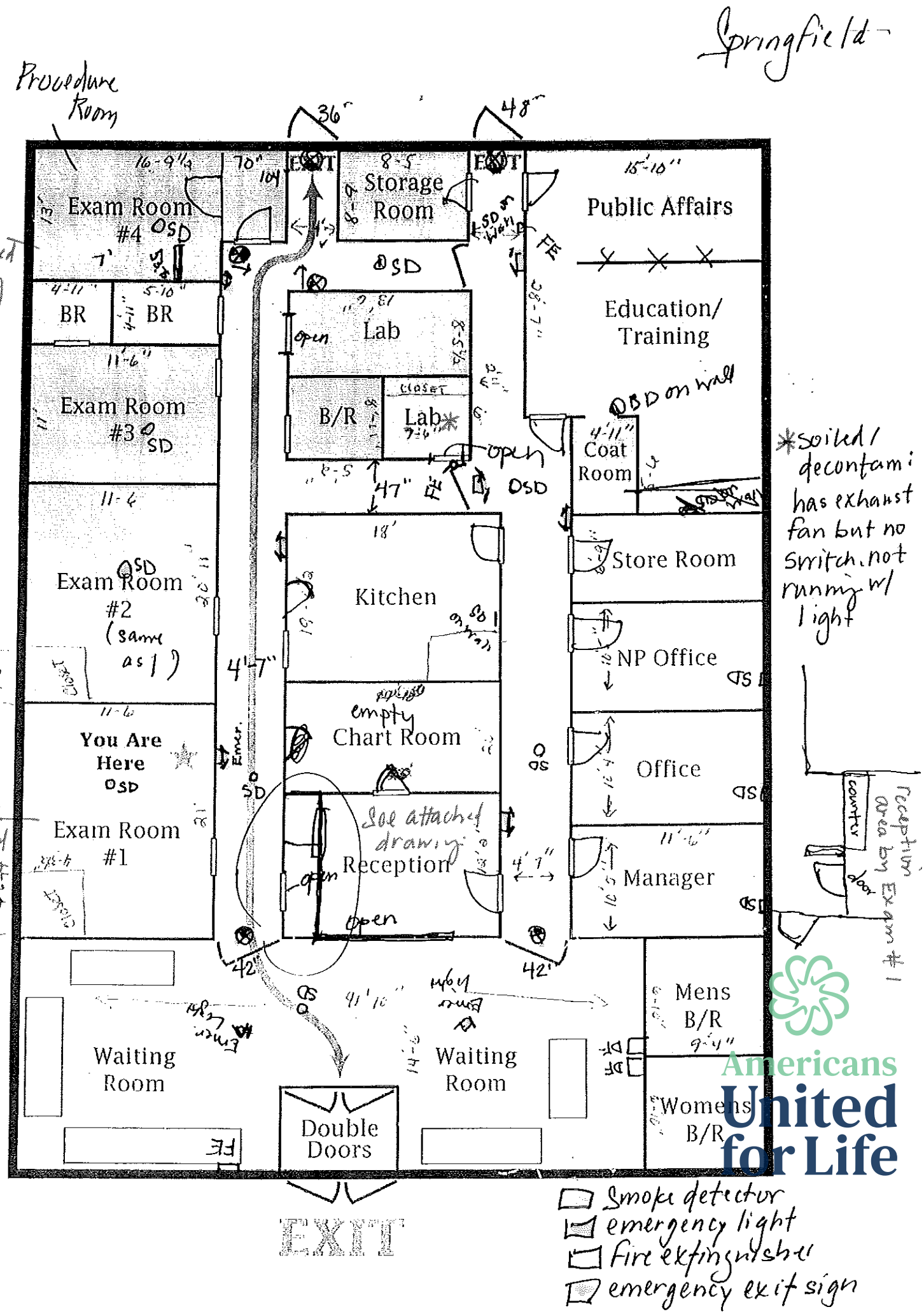
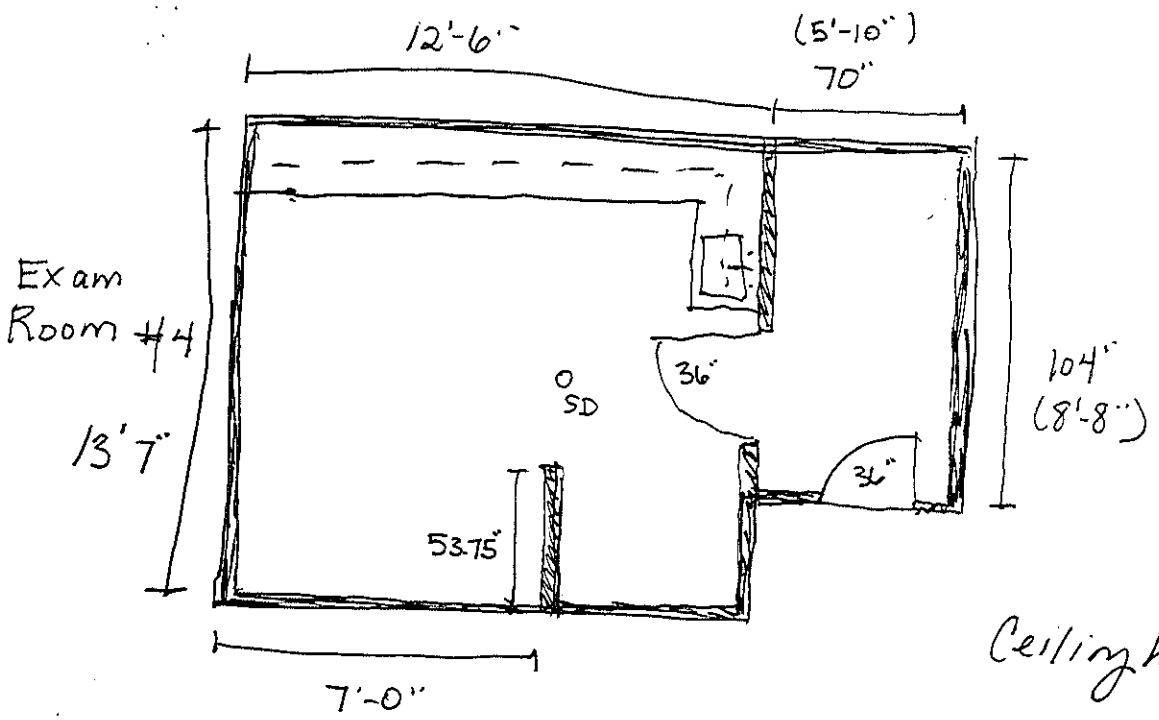

Springfield -
Procedure Room
36"
48"
Exam Room #4
OSD
7'
16-9 1/4
70"
10'
EXIT
8-5
Storage Room
EXIT
15'-10"
Public Affairs
See attached drawing
BR
BR
4'-11"
5-10"
OSD
Lab
open
8-5 1/2
Education/ Training
11'-6"
Exam Room #3
SD
B/R
Closet
Lab*
open
OSD
OSD on wall
4'-11"
Coat Room
*soiled/ decontami has exhaust fan but no switch. not running w/ light
11-4
47"
OSD
18'
Store Room
Exam Room #2 (same as 1)
Kitchen
NP Office
4'-7"
empty
Chart Room
11-6
You Are Here
OSD
Office
Emer.
SD
See attached drawing
Exam Room #1
See attached drawing
Reception
open
open
4'-1"
Manager
11'-6"
reception area by Exam #1
counter
42"
42"
Mens B/R
9'-4"
Waiting Room
Waiting Room
Womens B/R
Double Doors
FE
EXIT
Americans United for Life
Smoke detector
emergency light
fire extinguisher
emergency exit sign



- Possible procedure room

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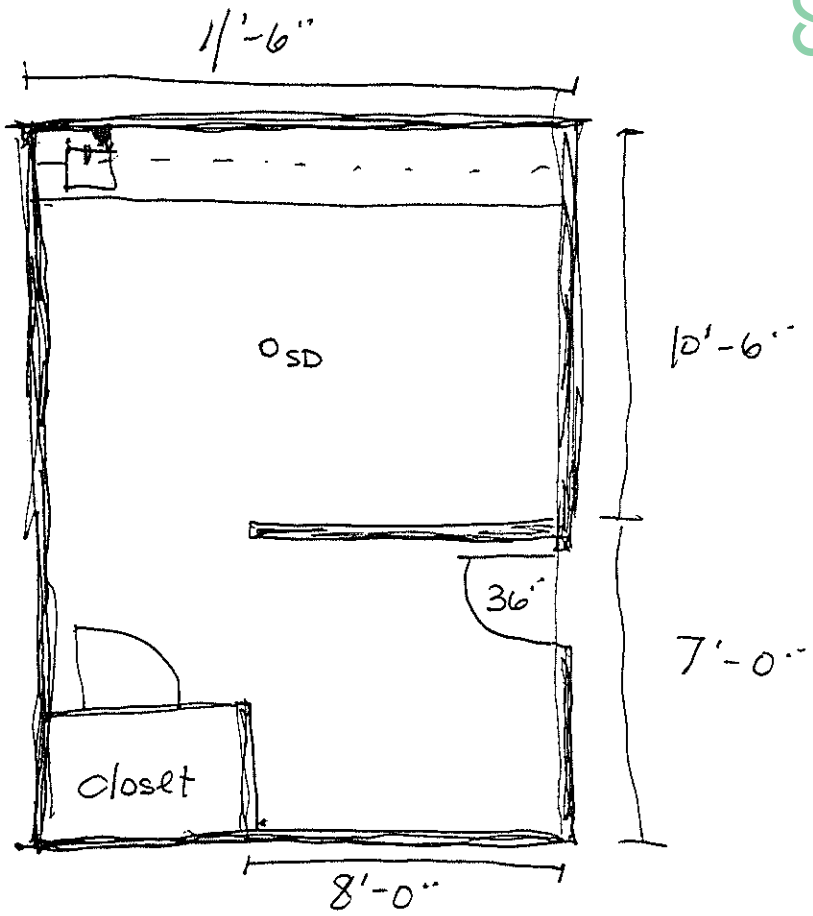
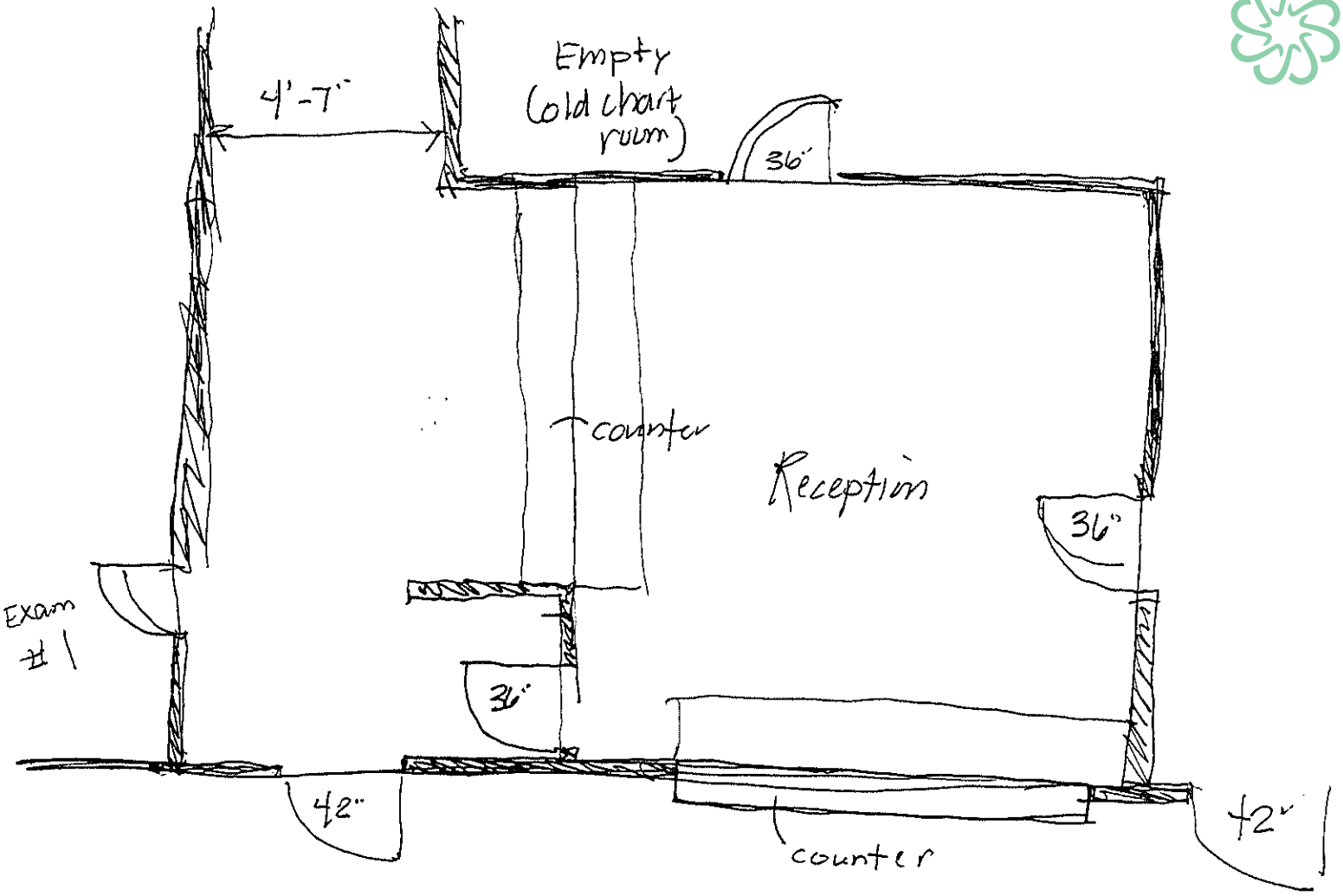
Exam Room #1 (#2 similar)





OSD

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

October 18, 2017

Janice Thomas, Administrator < Janice.thomas@ppslr.org >
Reproductive Health Services of Planned Parenthood of the St. Louis Region
626 E. Battlefield
Springfield, MO 65807

Re: Reproductive Health Services of Planned Parenthood – Springfield facility inspection

Dear Ms. Thomas:

The Department of Health and Senior Services received an application for licensure of the Springfield Planned Parenthood location as an abortion facility. Bureau of Ambulatory Care staff conducted an onsite initial inspection of the facility on October 10th and 11th of this year, in order to determine compliance with applicable statutes and regulations in effect at the time of the inspection.

Listed below are items the survey indicated were not in compliance with current rules. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued.

The facility was found to be out of compliance with the following:

19 CSR 30-30.050 Definitions and Procedures for Licensing Abortion Facilities
(1)(C) 3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.

-For three of three physicians (Staff AA, BB, CC) there was no recommendation by the medical staff or approval by the governing body for the physicians to be on the medical staff at this facility.
-The credentialing packets were incomplete and did not include:
**Information for Physician staff AA and BB did not include privileges requested and approved;*
**Physician staff BB did not have a BNDD/DEA registration; and*
**Physician staff CC had a date of 05/02/17 on a credentialing sheet but it was unclear if the privileges and approval were for this facility.*
-The meeting minutes provided, dated 01/06/2016, did not include names of physicians or identification of this facility for the section where it mentioned approval of attending physicians.

19 CSR 30-30.060(1)(B)13 A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs).

- No criminal background check on three of six employee files reviewed.

19 CSR 30-30.060(1)(B)8 The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.

- Medication prep/storage area was located in the lab area and at risk for cross-contamination;
- Pressed-board clipboard at registration desk with un-cleanable surface;
- Expired urine test strips;
- No recent infection control training for two of six employee files reviewed;
- Examination table in the ultrasound exam room had rust along the front edge of the table. There was damage to the wood at the base of the table and missing laminate on the front of the table, exposing pressed wood. All of these items created un-cleanable surfaces, posing an infection control risk; and
- Examination room #4 had a high level chemical disinfectant in an instrument soaking container located next to the hand washing sink. Used vaginal ultrasound probes were cleaned in the hand washing sink and decontaminated with a high level disinfectant in the examination room. The facility failed to place the probe in a leak-proof container or plastic bag and transport it to the soiled utility room to be cleaned and decontaminated.
- There were no smoke detectors in the training room, laboratory, store room and three offices.

19 CSR 30-30.060(3)(L) Emergency drugs, oxygen and intravenous fluids shall be available in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine and endotracheal equipment shall be located in the clinical area for immediate access.

- No suction machine; and
- No endotracheal equipment.

19 CSR 30-30.060(3)(C) A medical history shall be obtained and a health assessment including a pelvic examination shall be performed. There must be confirmation of pregnancy by clinical evidence and laboratory tests. The findings shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's chart.

***-** The facility failed to have policies and procedures in place that addressed pelvic examinations for medication abortions.*

19 CSR 30-30.060(4)(D) The following laboratory procedures shall be performed on every abortion patient: hematocrit; urinalysis, including pregnancy test; and Rh typing.

- The facility failed to stock the glucometer control testing solutions used to verify the glucometer is functioning properly before use.

Please respond in writing, providing documentation that each of these items has been fully addressed and corrected. If you have further questions, contact our office at 573-751-6083 or via email at BAC@health.mo.gov. Only upon successful completion of the revisit process can an abortion facility license be issued.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

December 21, 2017

Janice Thomas, Administrator *via email to*: < Janice.thomas@ppslr.org >
Reproductive Health Services of Planned Parenthood of the St. Louis Region
626 E. Battlefield
Springfield, MO 65807

Re: Reproductive Health Services of Planned Parenthood – Springfield facility inspection

Dear Ms. Thomas:

The Department of Health and Senior Services received an application for licensure of the Springfield Planned Parenthood location as an abortion facility. Bureau of Ambulatory Care staff conducted an onsite initial inspection of the facility on October 10th and 11th of this year, in order to determine compliance with applicable statutes and regulations in effect at the time of the inspection.

Listed below are items the survey indicated were not in compliance with current rules. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued. The facility was found to be out of compliance with the following:

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identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.

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- *The facility failed to have policies and procedures in place that addressed pelvic examinations for medication abortions.*

Note: In addition to the above items, since the date of the onsite visit, the department promulgated emergency rule ***19 CSR 30-30.061, Complication Plans for Certain Drug and Chemically Induced Abortions via Abortion Facilities***. This emergency rule was effective 11/3/17. To date, your facility has not submitted a proposed Complication Plan. Since the facility's plan is to perform only medication abortions for the time being, until your facility becomes compliant with that rule, the facility cannot be licensed as an abortion facility.

Please respond in writing, providing documentation that each of these items has been fully addressed and corrected. If you have further questions, contact our office at 573-751-6083 or via email at BAC@health.mo.gov . Only upon successful completion of the revisit process can an abortion facility license be issued.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

March 29, 2018

Janice Thomas
VP of Patient Services & Research
Reproductive Health Services of Planned Parenthood
4251 Forest Park Avenue
St. Louis, MO 63108

Via email to Janice.Thomas@ppslr.org

Re: Proposed complication plan for Springfield, Missouri facility

Dear Ms. Thomas:

The proposed complication plan submitted by Reproductive Health Services of Planned Parenthood for the Springfield facility on January 8, 2018, does not meet the requirements of Section 188.021, RSMo, and 19 CSR 30-30.061 in that:

The plan states that Dr. Grebe, a board-certified OB/GYN, will provide medical abortions in Springfield and treat the complications whenever possible. Whenever not possible, the plan states that either Dr. David Eisenberg or Dr. Orrin Moore respectively will personally treat complications at the Reproductive Health Services (RHS) facility in St. Louis or at a Comprehensive Health facility in Overland Park, Kansas. Dr. Eisenberg and the RHS facility are located over three hours driving time from the Springfield facility. Dr. Moore and the Overland Park facility are located over two-and-a-half hours driving time from the Springfield facility. As a result, neither Dr. Moore nor Dr. Eisenberg will be available to personally treat all complications in Dr. Grebe's absence, and patients who are not experiencing immediately life-threatening complications will be referred to the emergency room.

Additionally, the proposed plan fails to recognize the importance of the physician-patient relationship by providing for continuity of care and ensuring communication among the physician who induced the abortion and all subsequent health care providers involved in treating the patient's complication.

Because the facility's proposed plan does not meet the requirements of Section 188.021, RSMo, and 19 CSR 30-30.061, the Department cannot approve the plan. Accordingly, the Department cannot issue the facility a license until an approved plan is in place (and all other deficiencies have been corrected).
If the facility wishes to submit a new or revised plan, please send it to the Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102, or by email to John.Langston@health.mo.gov by April 15, 2018.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

Americans United for Life

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

June 1, 2018

Janice Thomas, VP of Patient Services & Research
Reproductive Health Services/
Planned Parenthood of the St Louis Region and Southwest Missouri
4251 Forest Park Ave, St. Louis MO 63108

Regarding Applications as Abortion Facilities for:

Springfield Planned Parenthood Clinic
626 East Battlefield
Springfield MO 65807

Joplin Planned Parenthood Clinic
710 Illinois Avenue
Joplin MO 64801

Janice Thomas:

1. During an interview on 5/29/2018 and confirmed on 5/30/18, St. Louis Planned Parenthood administrative staff stated that current plans to license the Springfield and Joplin locations as Abortion Facilities were indefinitely on hold.

2. By convention, the Bureau of Ambulatory Care holds applications open for new facilities for up to one year before requiring a new application package be submitted. The applications for the Springfield and Joplin locations were received by the Department of Health & Senior Services on 5/25/17, just over one year ago.

3. An initial inspection for the Springfield location was conducted October 2017. To date, an acceptable plan of correction for the items cited during that inspection has not been received. Moreover, a complete set of revised rules for abortion facilities went into effect on 4/30/2018, which would require a new inspection.

Due to the above items, the Bureau of Ambulatory Care is hereby closing the open Abortion Facility applications for the Springfield and Joplin Planned Parenthood Clinics. You may submit new applications at any point you believe the facilities are prepared to be in compliance with all applicable laws and rules for Abortion Facilities in Missouri.

If you have additional questions, do not hesitate to contact our office via email at BAC@health.mo.gov or by phone at 573-751-6083.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Planned Parenthood®
Care. No matter what.

Planned Parenthood of the St. Louis Region and Southwest Missouri

Administrative Office
4251 Forest Park Avenue
St. Louis, MO 63108
p: 314.531.7526 | f: 314.531.9731
www.plannedparenthood.org/stlouis

February 1, 2019

Via email to: William.Koebel@health.mo.gov

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: *Request for Deviation*

Dear Mr. Koebel:

Pursuant 19 CSR 30-30.070(2), I write to request deviations/waivers of certain physical standards for Reproductive Health Services of Planned Parenthood of the St. Louis Region's (RHS) health center in Springfield.

The physical facility restrictions in 19 CSR 30-30.070 prevent us from providing surgical abortion in our Springfield health center. RHS remains committed to providing abortion services to the women of Southwest Missouri, and therefore by this letter seeks waivers of those requirements it cannot meet. We request the Department "exercise[] the Waiver Provision" "with sufficient flexibility" and reasonableness. *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, 903 F.3d 750, 756–57 (8th Cir. 2018).

Abortion Safety

As you know, RHS has safely provided abortion services in Missouri for many years. The physical facility restrictions are medically unnecessary and do not improve the health and safety of our patients seeking abortion care. Indeed, the Department has recognized as much when it waived a number of medically unnecessary restrictions in a 2010 settlement with the Columbia health center.

Abortion is one of the safest medical procedures in the United States. As the National Academies of Sciences, Engineering, and Medicine—which recently conducted a systematic review of the safety and quality of care of abortion in the United States—found, abortion in the United States is safe. In particular, first-trimester aspiration

abortion, which we seek to provide in the Springfield health center, "is a minimally invasive and commonly used gynecological procedure," including "in cases of early pregnancy loss (miscarriage)."[1] Aspiration abortion is effective at terminating an early pregnancy in more than 99% of those provided, and complications from first-trimester aspiration abortion occur in approximately 1.26% of patients—and serious complication in less than 0.02%.[2] Aspiration abortion may require no or only minimal sedation.

As the National Academies observed, "[a]spiration abortions are performed safely in office and clinic settings."[3] Abortion-specific regulations—such as the physical facility restrictions in 19 CSR 30-30.070—serve only to "diminish" the quality of care women receive by "limit[ing] the number of available providers."[4]

Requested Waivers

Against the backdrop of abortion's demonstrated safety, and given that the current facility is sufficient to protect patient health and safety, we make the following waiver requests. We note at the outset that we are committed to working with the Department on these issues so that we can begin providing abortion services to our patients at the Springfield health center. We also note that the Springfield facility meets many of the requirements in 19 CSR § 30-30.070(4), which applies to facilities existing at the time the regulation was adopted, and therefore, demonstrates the Department's understanding that these provisions are sufficient to protect patient health and safety.

1. **Patient-Serving Corridors and Doors**

Subsections 30-30.70(3)(B) & (C) require patient-serving corridors be at least 6' wide and doors through which patients pass be at least 44" wide and of solid-core construction. Patient-serving corridors at the Springfield center are 4'7" wide and doors through which patients pass are at least 32" wide and of hollow-core construction.

The Springfield health center's current system of corridors and doors adequately protect patient health and safety by allowing a patient to be moved by stretcher from any point in the facility to the outside via the main entrance. Indeed, the Springfield health center's current corridors and doors comply with the requirement at 19 CSR § 30-30.070(4)(B) that the system of corridors and passageways be "adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit." We also note that the Department agreed to a similar corridor dimension for the Columbia health center in a 2010 settlement agreement.

[1] Nat'l Acad. of Sciences, Engineering & Medicine, The Safety and Quality of Abortion Care in the United States 2-12 (2018).
[2] *Id.* at 2-12 to 2-13 (citing Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 124 Obstetrics & Gynecology 175 (2015)).
[3] *Id.* at S-8.
[4] *Id.* at S-10.

2. Construction Type

Subsection 30-30.70(3)(D) requires one-story buildings be at least of Type II (111) protected noncombustible construction as described in *Standard on Types of Building Construction* 1979 published by the National Fire Protection Association. The Springfield facility is of Type V (100) unprotected combustible construction.

The Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The higher fire-safety rating is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

3. Fire Alarm

Subsection 30-30.70(3)(H) requires a manual fire alarm break station be located near each exit and connected to a local audible alarm that can be heard throughout the facility. The Springfield health center does not have manual fire alarm break stations at each exit.

The Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The requirement is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

4. Scrub Station

Subsection 30-30.70(3)(L) requires a scrub-up facility be knee- or foot-operated and be located outside the procedure room. The Springfield health center has a scrub station located inside the procedure room. The requirement that the scrub station be located outside the procedure room does not protect patient health or safety. The Springfield

center complies with the requirement in 19 CSR § 30-30.070(4)(F) that the scrub-up facility be located convenient to the procedure room.[5]

5. Procedure Room

Subsection 30-30.70(3)(M) requires that all procedure rooms be a minimum of 12' length and width, 9' ceiling height, and doors with a width of at least 44". The Springfield facility's procedure room's dimensions are 12'6" by 11'6", ceiling height of 7'9", and door width of 36".

The dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

Further, the Springfield health center's existing procedure room meets the requirement at 19 CSR § 30-30.070(4)(E) that it be "adequately equipped, supplied, and staffed to safely perform abortions," which the Department has determined is sufficient to protect patient health and safety; this requirement does not specify minimum dimensions. The room is of sufficient size to fit a gynecologic examining table with accessories, a closed cabinet for equipment, and tables to hold an emergency tray and other necessary equipment.

Requiring compliance with the nine-foot ceiling height would not advance patient health and safety, because such ceiling height requirements generally are intended to facilitate installation of a ceiling-mounted surgical light. These lights would not be appropriate to the procedures done at the Springfield health center, for the reasons given below under request no. 9. Requiring compliance with the 44" door width would not advance patient health and safety at the Springfield health center because, as discussed above under request no. 1, the current system of corridors and doors allows rapid patient evacuation in the event of an emergency. Finally, we note that the Department agreed to similar dimensions of 12' length, 9' 0.5" width, and 8' 6'" height for the Columbia health center in a 2010 settlement agreement.

6. Recovery Room

Subsection 30-30.70(3)(N) requires the recovery room be of sufficient size for four recovery recliners or beds with 3' of clear space on both sides and at the foot of each recliner or bed.

The Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner. We do not anticipate scheduling—and will agree to not schedule—more patients than the recovery room can accommodate. We note that the Department recently approved a deviation from this requirement for the Columbia facility to permit three recliners.

[5] We acknowledge our current scrub sink is not knee- or foot-operated. We will replace the current sink with a knee- or foot-operated if the Department approves this waiver.

7. HVAC

Subsection 30-30.70(3)(O) requires the procedure and recovery rooms be provided with a minimum of six air changes per hour and filtered through a filter with at least a twenty-five percent (25%) efficiency rating. The Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. This requirement is not necessary for patient health or safety, particularly since surgical abortion does not require a sterile operating room environment, as demonstrated by its omission in 19 CSR § 30-30.070(4).

8. Personnel-Change Room

Subsection 30-30.70(3)(P) requires personnel-change rooms be provided for each sex, located convenient to the procedure room, and equipped with a toilet and lavatory. The Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory. We note that the Department agreed to a similar deviation for the Columbia health center in a 2010 settlement agreement.

9. Ceiling-Mounted Surgical Light

Subsection 30-30.70(3)(R) requires the the procedure room be equipped with a ceiling-mounted light. The Springfield facility's procedure room would be equipped with a walled-mounted surgical light, which is better angled for the procedures that would be provided. We note that the Department agreed to similar deviation for the Columbia health center in a 2010 settlement agreement.

10. Sterilizing Room

Subsection 30-30.70(3)(V) requires that air pressure in the sterilizing room be positive in relation to adjacent areas. The air pressure in the Springfield health center's sterilizing room is not positive in relation to adjacent areas. This requirement is not necessary for patient health or safety, as demonstrated by its omission in 19 CSR § 30-30.070(4).

11. Patient-Change Rooms

Subsection 30-30.70(3)(Y) requires there be at least two patient-change rooms with secure storage for personal effects. The Springfield facility has one patient-change room. We note that the Department agreed to deviation for the Columbia health center in a 2010 settlement agreement such that there could be one patient-change room if the patient traveled with her belongings in a secure container. We will agree to do the same or provide the patient with secure storage in the patient-change room.

Burdens

Complying with the physical facility requirements in 19 CSR 30-30.070 at our Springfield facility would be prohibitively expensive and burdensome. A recent survey of the facility by a licensed architect found that it would cost $2.26 million to remodel the Springfield health center to meet the requirements in 19 CSR 30-30.070, which is approximately the same amount to construct a new facility. Construction would take

approximately eight months to complete and include complete removal and installation of the roof and exterior walls. As a result, such construction would completely disrupt the critical health services currently provided there, including family planning services that help prevent unplanned pregnancies.

Please let me know if you have any questions regarding this request. I look forward to hearing your prompt response.

Sincerely,

Janice Thomas
Vice President of Patient Services & Research

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

April 18, 2019

Cathy Williams, Interim President & CEO
Reproductive Health Services of Planned Parenthood
425 Forest Park Avenue
St. Louis, MO 63108

Re: Request for Deviation (RHS Health Center – Springfield, MO)

Dear Ms. Williams:

On February 1, 2019, Reproductive Health Services (RHS) submitted a Request for Deviations from some requirements of 19 CSR 30-30.070, for RHS' health center in Springfield, Missouri (attached).

The Department requested that RHS provide a code review sheet and architectural plans, as the request lacked sufficient information for DHSS to reasonably approve or deny the requests. In response, on February 8, 2019, RHS provided a facility floor plan (attached). The additionally provided information remained insufficient to make a determination. A mutually agreeable onsite walk-through was arranged for March 5, 2019, in order to gather sufficient information to respond to the submitted request.

On March 5, 2019, DHSS staff conducted a walk-through of the Springfield facility. RHS facilities manager, Chris Trull, represented RHS. The walk-through identified additional concerns related to the initial request submitted. Mr. Trull informed DHSS Deputy Administrator, David Lanigan, that the "measurements are not accurate" in the floor plan and request. Additionally, the floor plan did not accurately reflect additional walls inside the exam rooms. Furthermore, Mr. Trull was not familiar with RHS' plan regarding room locations, as identified in the request. Please find the below determinations regarding your request:

1. **Patient-Serving Corridors and Doors**

19 CSR 30-30.070(3)(B) & (C), states, *"(B) Corridors serving patients shall be at least six feet (6') wide; (C) All doors through which patients pass shall be at least forty-four inches (44") wide and of solid-core construction;"*

The RHS request indicates that patient-serving corridors are 4'7" wide and pass through doors are at least 32" wide and of hollow-core construction. The RHS request further asserts that the Springfield health center's current corridors and doors comply with the requirement at 19 CSR 30-30.070 (4)(B).

DHSS staff observed that the passageways at the facility are not adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit. The procedure room is constructed with barriers to maneuverability (inner walls and small spaces) not shown on the provided floor plan. As constructed, the layout and location of the existing doors into this

room do not open fully to allow for a wheelchair or a gurney to be easily moved out of the room in an emergency. In addition, the corridors serving patients and the door widths of the patient rooms other than the procedure room (noted as Exam Rooms #1, #2, and #3 on the floor plan provided to DHSS) are not of sufficient size to allow a stretcher to be promptly maneuvered in and a patient on a stretcher to be promptly maneuvered out of those rooms to a street-level exit. Only one exterior door meets the requirements of being 44" or wider.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(B) & (C). DHSS is willing to reconsider this request if RHS provides an adequate remediation plan that ensures prompt maneuverability of a patient on a stretcher into and out of the procedure room and other patient rooms in an emergency event.

2. **Construction Type**

19 CSR 30-30.070(3)(D) states, "*(D) One- (1-) story buildings shall be at least of Type II (111) protected noncombustible construction as described in Standard on Types of Building Construction 1979 published by the National Fire Protection Association;*"

The RHS request indicates that the Springfield facility is of "Type V (100) unprotected combustible construction." The RHS request further asserts that the Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the construction type of the facility is Type V (000), unprotected combustible construction. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility's construction is insufficient to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(D). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

3. **Fire Alarm**

19 CSR 30-30.070(3) (H) states, "*(H) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;*".

The RHS request indicates that the Springfield facility does not have manual fire alarm break stations at each exit. The RHS request further asserts that the Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the facility lacks the required alarm break stations near each exit, connected to a local audible alarm. The facility is currently protected by three ABC-fire extinguishers and spot-type smoke detectors located in most, but not all rooms. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility is insufficiently equipped with fire alarm break stations to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(H). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

4. **Scrub Station**

19 CSR 30-30.070(3) (L) states, "*(L) Scrub-up facilities shall be knee- or foot-operated and provided at the rate of one (1) per procedure room. Scrub-up facilities shall be located outside but immediately available to the procedure room;*"

The RHS request indicates that the Springfield facility does have a scrub station located inside the room identified as the procedure room.

DHSS staff confirmed that the facility has a sink in the procedure room that is not knee-or-foot operated, as required.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(L), provided the current sink is replaced with a knee or foot operated scrub station, as noted in the request and it is physically separated by a wall or partition from the patient and procedure equipment to prevent contamination while scrubbing for procedures.

5. **Procedure Room**

19 CSR 30-30.070(3) (M) states, "*(M) Procedure rooms shall have the following: 1. A minimum length and width of twelve feet (12'); 2. A minimum ceiling height of nine feet (9'); 3. A door with a minimum width of forty-four inches (44"); and 4. There shall be no windows in the room except there may be a fixed-view window in the wall between the procedure room and the adjacent corridor;*"

The RHS request indicates that the Springfield facility's procedure room was 12'6" by 11'6", the ceiling height is 7'9 and the door width is 36." The RHS request further asserts that the dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

RHS representative, Mr. Trull, identified Exam Room #4 as the procedure room. The measurements and configuration of Exam Room #4 differed from the floor plan provided to DHSS. According to the floor plan, the measurements of the room are "16-9 ½" by "13'". Further, the floor plan nor the measurements in the waiver request account for interior walls that break up the room, limiting mobility. Mr. Trull, acknowledged the measurements provided by RHS were "not accurate." DHSS staff observed that the procedure table is located in an alcove that is 7' in width and separated from an adjacent open area with a 4'6" wing-wall. The identified procedure room is insufficient in size and configuration to allow medical staff to move freely in the event of an emergency (see attached photos).

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(M)(1) and (3). DHSS approves the request for deviation from 19 CSR 30-30.070(3)(M)(2). DHSS is willing to reconsider the denied aspects of this request if RHS provides an adequate remediation plan that ensures prompt

maneuverability of a patient on a stretcher into and out of the procedure room in the event of an emergency.

6. **Recovery Room**

19 CSR 30-30.070 (3) (N) states, "*(N) The recovery room shall be separated from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner;*"

The RHS request indicates that the Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner.

RHS representative, Mr. Trull, could not identify which room would be utilized as the recovery room. Mr. Trull stated he was "not sure of the plan" and didn't think RHS had decided where the room would be located. Without knowing which room would be the recovery room, DHSS cannot determine whether a deviation is warranted.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(N). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room.

7. **HVAC**

19 CSR 30-30.070 (3)(O) states, "*(O) The procedure room and recovery room shall be provided with a minimum of six (6) air changes per hour. Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rating;*"

The RHS request indicates that the Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. Mr. Trull was unable to provide documentation of the facility's current air exchange rate or current efficiency rating for evaluation. Further, Mr. Trull could not identify the location of the recovery room, which restricts DHSS's ability to determine whether a deviation is warranted.

Lastly, the fact that DHSS determined in 1987 that the requirements for then-existing abortion facilities need not include a minimum number of air changes per hour or a filter with a minimum efficiency rating does not mean—as suggested in the RHS request—that requiring these things for facilities constructed after the rule was promulgated in 1987 has no effect on improving patient health or safety. This provision of this rule, like others discussed in this letter, was promulgated in 1987 under DHSS's authority in section 197.225 RSMo to assure quality patient care through standards that insure the health, safety, and comfort of patients. Requirements of minimum air changes per hour are also required by DHSS for ambulatory surgical centers generally and birthing centers. Any deviations from this rule, as with others, would need to be based on a legitimate and persuasive reason provided by the requester. Here, the only reason provided for a deviation is that DHSS does not require in the rule minimum air changes and filter efficiency ratings for then-existing abortion facilities in 1987. This reason is not sufficient. The reported cost (as alleged in the request) of $2.26 million to comply with the rule in total, moreover, provides no indication how much of that total would be attributable to these particular

requirements. And as noted above, Mr. Trull could not provide documentation showing the current ventilation capabilities. Under these circumstances, DHSS cannot reasonably grant a deviation from a rule designed to insure the health, safety, and comfort of patients.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(O). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room and provides adequate information that allows DHSS to meaningfully assess the Springfield facility's current air exchange rate and efficiency rating.

8. **Personnel-Change Room**

19 CSR 30-30.070 (3) (P) states, "*(P) Personnel change rooms shall be provided for each sex and located convenient to the procedure room. Each change room shall be equipped with a toilet and lavatory;*"

The RHS request indicates that the Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory.
RHS representative, Mr. Trull, identified a restroom, in close proximity to the procedure room as a personnel-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(P).

9. **Ceiling-Mounted Surgical Light**

19 CSR 30-30.070 (3) (R) states, "*(R) The procedure room shall be equipped with a ceiling-mounted surgical light, operating table or a conventional gynecological examining table with accessories, closed cabinets for equipment, and sufficient tables to hold an emergency tray and other necessary equipment;*"

The RHS request indicates that the Springfield facility will equip the procedure room with a wall-mounted surgical light, which would be better angled for the procedures they provide.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(R) based on the current configuration and available space within the identified procedure room, which is limited by an interior wall directly to the left of the room entrance. This wall does not allow sufficient space in the room for mounting the surgical light on the wall. DHSS is willing to reconsider this request if modifications are made to the room that allow sufficient space to mount the surgical light on the wall.

10. **Sterilization Room**

19 CSR 30-30.070 (3) (V) states, "*(V) The sterilizing room shall be equipped with a steam sterilizer, counter and sink, and storage space for clean supplies. Air pressure in this room shall be positive in relation to adjacent areas;*"

The RHS request indicates that the air pressure in the Springfield facility's sterilizing room is not positive in relation to the adjacent areas. Mr. Trull was unable to identify the location of the sterilization room or provide documentation of the room's current air pressure for evaluation. As with the recovery

room, this restricts DHSS's ability to determine whether a deviation is warranted. And for similar reasons set forth above with respect to the request for deviation from the ventilation requirements, the mere fact that DHSS did not express this as a requirement for abortion facilities in existence when the rule was promulgated in 1987 is not sufficient reason to justify deviation from the rule.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(V). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the sterilizing room and provides adequate information that allows DHSS to meaningfully assess the sterilizing room's air pressure in relation to adjacent areas.

11. **Patient-Change Rooms**

19 CSR 30-30.070 (3) (Y) states, "*(Y) At least two (2) patient change rooms with secure storage for personal effects shall be provided;*"

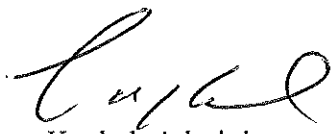
The RHS request indicates that the Springfield facility has one patient-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(Y) under the condition that patient belongings travel with the patient in a secure container, it uses only one (1) procedure room and does not use the procedure room as the change room.

The deviation approvals contained in this correspondence may be revoked any time DHSS determines: (1) that patient care or safety may be compromised, (2) that the facility is not in full compliance with applicable rules, or (3) the facility fails to adhere to all conditions of the approved deviations.

Thank you again for your willingness to coordinate an on-site walk-through of the Springfield facility. Should you have further questions regarding this letter, please contact David Lanigan at David.Lanigan@health.mo.gov or by calling (573) 526-1864.

Sincerely,



William Koebel, Administrator
Section for Health Standards and Licensure
Division of Regulation and Licensure
Department of Health and Senior Services

Americans United for Life

Planned Parenthood
Care. No matter what.

Planned Parenthood of the St. Louis Region and Southwest Missouri

Administrative Office
4251 Forest Park Avenue
St. Louis, MO 63108

p. 314.531.7526 | f. 314.531.9731
www.plannedparenthood.org/stlouis

February 1, 2019

Via email to: William.Koebel@health.mo.gov

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: *Request for Deviation*

Dear Mr. Koebel:

Pursuant 19 CSR 30-30.070(2), I write to request deviations/waivers of certain physical standards for Reproductive Health Services of Planned Parenthood of the St. Louis Region's (RHS) health center in Springfield.

The physical facility restrictions in 19 CSR 30-30.070 prevent us from providing surgical abortion in our Springfield health center. RHS remains committed to providing abortion services to the women of Southwest Missouri, and therefore by this letter seeks waivers of those requirements it cannot meet. We request the Department "exercise[] the Waiver Provision" "with sufficient flexibility" and reasonableness. *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, 903 F.3d 750, 756–57 (8th Cir. 2018).

Abortion Safety

As you know, RHS has safely provided abortion services in Missouri for many years. The physical facility restrictions are medically unnecessary and do not improve the health and safety of our patients seeking abortion care. Indeed, the Department has recognized as much when it waived a number of medically unnecessary restrictions in a 2010 settlement with the Columbia health center.

Abortion is one of the safest medical procedures in the United States. As the National Academies of Sciences, Engineering, and Medicine—which recently conducted a systematic review of the safety and quality of care of abortion in the United States—found, abortion in the United States is safe. In particular, first-trimester aspiration

abortion, which we seek to provide in the Springfield health center, "is a minimally invasive and commonly used gynecological procedure," including "in cases of early pregnancy loss (miscarriage)."[1] Aspiration abortion is effective at terminating an early pregnancy in more than 99% of those provided, and complications from first-trimester aspiration abortion occur in approximately 1.26% of patients—and serious complication in less than 0.02%.[2] Aspiration abortion may require no or only minimal sedation.

As the National Academies observed, "[a]spiration abortions are performed safely in office and clinic settings."[3] Abortion-specific regulations—such as the physical facility restrictions in 19 CSR 30-30.070—serve only to "diminish" the quality of care women receive by "limit[ing] the number of available providers."[4]

Requested Waivers

Against the backdrop of abortion's demonstrated safety, and given that the current facility is sufficient to protect patient health and safety, we make the following waiver requests. We note at the outset that we are committed to working with the Department on these issues so that we can begin providing abortion services to our patients at the Springfield health center. We also note that the Springfield facility meets many of the requirements in 19 CSR § 30-30.070(4), which applies to facilities existing at the time the regulation was adopted, and therefore, demonstrates the Department's understanding that these provisions are sufficient to protect patient health and safety.

1. **Patient-Serving Corridors and Doors**

Subsections 30-30.70(3)(B) & (C) require patient-serving corridors be at least 6' wide and doors through which patients pass be at least 44" wide and of solid-core construction. Patient-serving corridors at the Springfield center are 4'7" wide and doors through which patients pass are at least 32" wide and of hollow-core construction.

The Springfield health center's current system of corridors and doors adequately protect patient health and safety by allowing a patient to be moved by stretcher from any point in the facility to the outside via the main entrance. Indeed, the Springfield health center's current corridors and doors comply with the requirement at 19 CSR § 30-30.070(4)(B) that the system of corridors and passageways be "adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit." We also note that the Department agreed to a similar corridor dimension for the Columbia health center in a 2010 settlement agreement.

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[1] Nat'l Acad. of Sciences, Engineering & Medicine, The Safety and Quality of Abortion Care in the United States 2-12 (2018).
[2] *Id.* at 2-12 to 2-13 (citing Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 124 Obstetrics & Gynecology 175 (2015)).
[3] *Id.* at S-8.
[4] *Id.* at S-10.

2. Construction Type

Subsection 30-30.70(3)(D) requires one-story buildings be at least of Type II (111) protected noncombustible construction as described in *Standard on Types of Building Construction* 1979 published by the National Fire Protection Association. The Springfield facility is of Type V (100) unprotected combustible construction.

The Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The higher fire-safety rating is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

3. Fire Alarm

Subsection 30-30.70(3)(H) requires a manual fire alarm break station be located near each exit and connected to a local audible alarm that can be heard throughout the facility. The Springfield health center does not have manual fire alarm break stations at each exit.

The Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The requirement is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

4. Scrub Station

Subsection 30-30.70(3)(L) requires a scrub-up facility be knee- or foot-operated and be located outside the procedure room. The Springfield health center has a scrub station located inside the procedure room. The requirement that the scrub station be located outside the procedure room does not protect patient health or safety. The Springfield

center complies with the requirement in 19 CSR § 30-30.070(4)(F) that the scrub-up facility be located convenient to the procedure room.[5]

5. Procedure Room

Subsection 30-30.70(3)(M) requires that all procedure rooms be a minimum of 12' length and width, 9' ceiling height, and doors with a width of at least 44". The Springfield facility's procedure room's dimensions are 12'6" by 11'6", ceiling height of 7'9", and door width of 36".

The dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

Further, the Springfield health center's existing procedure room meets the requirement at 19 CSR § 30-30.070(4)(E) that it be "adequately equipped, supplied, and staffed to safely perform abortions," which the Department has determined is sufficient to protect patient health and safety; this requirement does not specify minimum dimensions. The room is of sufficient size to fit a gynecologic examining table with accessories, a closed cabinet for equipment, and tables to hold an emergency tray and other necessary equipment.

Requiring compliance with the nine-foot ceiling height would not advance patient health and safety, because such ceiling height requirements generally are intended to facilitate installation of a ceiling-mounted surgical light. These lights would not be appropriate to the procedures done at the Springfield health center, for the reasons given below under request no. 9. Requiring compliance with the 44" door width would not advance patient health and safety at the Springfield health center because, as discussed above under request no. 1, the current system of corridors and doors allows rapid patient evacuation in the event of an emergency. Finally, we note that the Department agreed to similar dimensions of 12' length, 9' 0.5" width, and 8' 6"' height for the Columbia health center in a 2010 settlement agreement.

6. Recovery Room

Subsection 30-30.70(3)(N) requires the recovery room be of sufficient size for four recovery recliners or beds with 3' of clear space on both sides and at the foot of each recliner or bed.

The Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner. We do not anticipate scheduling—and will agree to not schedule—more patients than the recovery room can accommodate. We note that the Department recently approved a deviation from this requirement for the Columbia facility to permit three recliners.

[5] We acknowledge our current scrub sink is not knee- or foot-operated. We will replace the current sink with a knee- or foot-operated if the Department approves this waiver.

7. HVAC

Subsection 30-30.70(3)(O) requires the procedure and recovery rooms be provided with a minimum of six air changes per hour and filtered through a filter with at least a twenty-five percent (25%) efficiency rating. The Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. This requirement is not necessary for patient health or safety, particularly since surgical abortion does not require a sterile operating room environment, as demonstrated by its omission in 19 CSR § 30-30.070(4).

8. Personnel-Change Room

Subsection 30-30.70(3)(P) requires personnel-change rooms be provided for each sex, located convenient to the procedure room, and equipped with a toilet and lavatory. The Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory. We note that the Department agreed to a similar deviation for the Columbia health center in a 2010 settlement agreement.

9. Ceiling-Mounted Surgical Light

Subsection 30-30.70(3)(R) requires the the procedure room be equipped with a ceiling-mounted light. The Springfield facility's procedure room would be equipped with a walled-mounted surgical light, which is better angled for the procedures that would be provided. We note that the Department agreed to similar deviation for the Columbia health center in a 2010 settlement agreement.

10. Sterilizing Room

Subsection 30-30.70(3)(V) requires that air pressure in the sterilizing room be positive in relation to adjacent areas. The air pressure in the Springfield health center's sterilizing room is not positive in relation to adjacent areas. This requirement is not necessary for patient health or safety, as demonstrated by its omission in 19 CSR § 30-30.070(4).

11. Patient-Change Rooms

Subsection 30-30.70(3)(Y) requires there be at least two patient-change rooms with secure storage for personal effects. The Springfield facility has one patient-change room. We note that the Department agreed to deviation for the Columbia health center in a 2010 settlement agreement such that there could be one patient-change room if the patient traveled with her belongings in a secure container. We will agree to do the same or provide the patient with secure storage in the patient-change room.

Burdens

Complying with the physical facility requirements in 19 CSR 30-30.070 at our Springfield facility would be prohibitively expensive and burdensome. A recent survey of the facility by a licensed architect found that it would cost $2.26 million to remodel the Springfield health center to meet the requirements in 19 CSR 30-30.070, which is approximately the same amount to construct a new facility. Construction would take

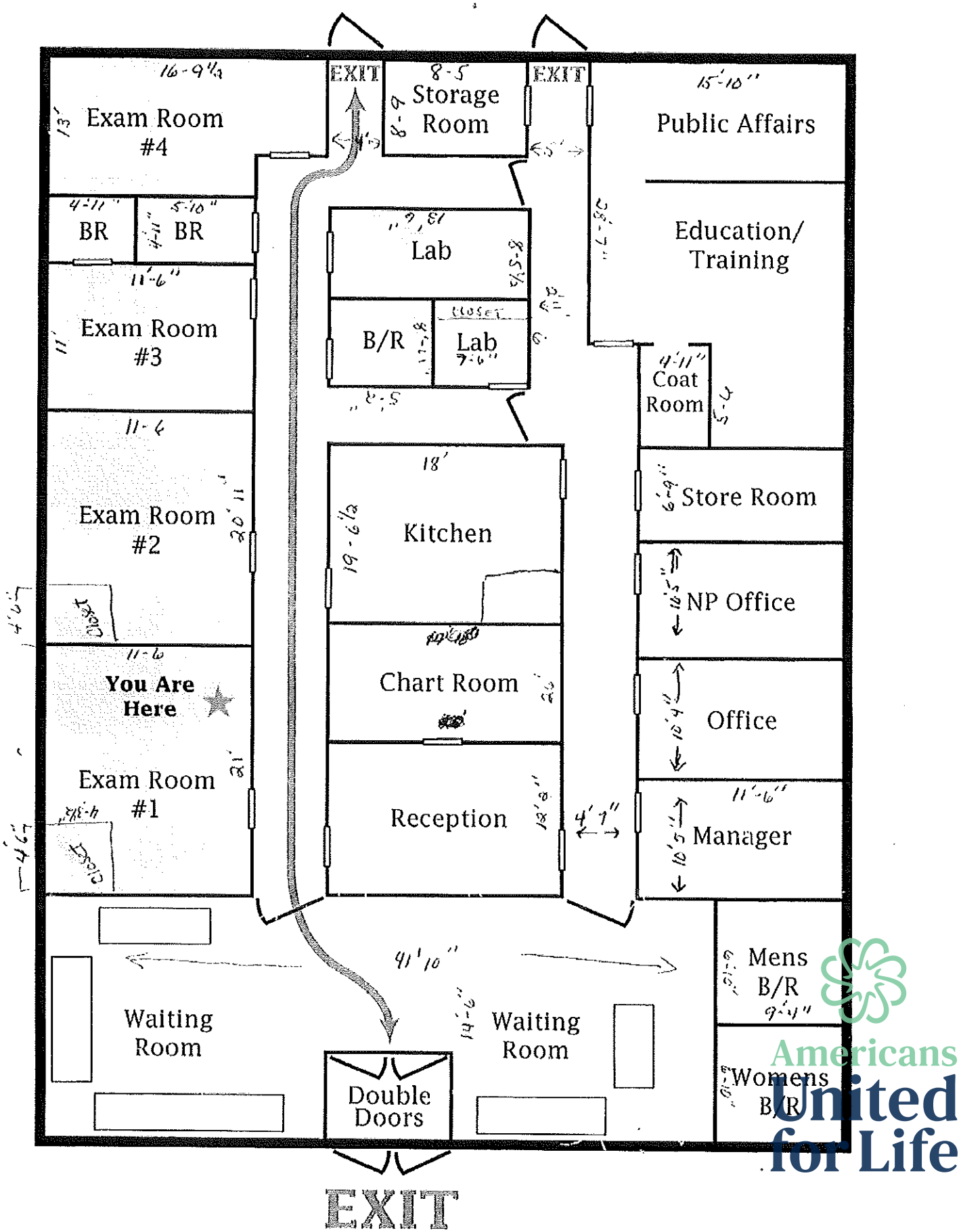
approximately eight months to complete and include complete removal and installation of the roof and exterior walls. As a result, such construction would completely disrupt the critical health services currently provided there, including family planning services that help prevent unplanned pregnancies.

Please let me know if you have any questions regarding this request. I look forward to hearing your prompt response.

Sincerely,

Janice Thomas
Vice President of Patient Services & Research

Americans United for Life



Americans
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Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

December 21, 2017

Janice Thomas, Administrator *via email to*: < Janice.thomas@ppslr.org >
Reproductive Health Services of Planned Parenthood of the St. Louis Region
626 E. Battlefield
Springfield, MO 65807

Re: Reproductive Health Services of Planned Parenthood – Springfield facility inspection

Dear Ms. Thomas:

The Department of Health and Senior Services received an application for licensure of the Springfield Planned Parenthood location as an abortion facility. Bureau of Ambulatory Care staff conducted an onsite initial inspection of the facility on October 10th and 11th of this year, in order to determine compliance with applicable statutes and regulations in effect at the time of the inspection.

Listed below are items the survey indicated were not in compliance with current rules. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued. The facility was found to be out of compliance with the following:

19 CSR 30-30.050 Definitions and Procedures for Licensing Abortion Facilities
(1)(C) 3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.

-For three of three physicians (Staff AA, BB, CC) there was no recommendation by the medical staff or approval by the governing body for the physicians to be on the medical staff at this facility.
-The credentialing packets were incomplete and did not include:
**Information for Physician staff AA and BB did not include privileges requested and approved;*
**Physician staff BB did not have a BNDD/DEA registration; and*
**Physician staff CC had a date of 05/02/17 on a credentialing sheet but it was unclear if the privileges and approval were for this facility.*
-The meeting minutes provided, dated 01/06/2016, did not include names of physicians or identification of this facility for the section where it mentioned approval of attending physicians.

19 CSR 30-30.060(1)(B)13 A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs).

- No criminal background check on three of six employee files reviewed.

19 CSR 30-30.060(1)(B)8 The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be

identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.

- Medication prep/storage area was located in the lab area and at risk for cross-contamination;
- Pressed-board clipboard at registration desk with un-cleanable surface;
- Expired urine test strips;
- No recent infection control training for two of six employee files reviewed;
- Examination table in the ultrasound exam room had rust along the front edge of the table. There was damage to the wood at the base of the table and missing laminate on the front of the table, exposing pressed wood. All of these items created un-cleanable surfaces, posing an infection control risk; and
- Examination room #4 had a high level chemical disinfectant in an instrument soaking container located next to the hand washing sink. Used vaginal ultrasound probes were cleaned in the hand washing sink and decontaminated with a high level disinfectant in the examination room. The facility failed to place the probe in a leak-proof container or plastic bag and transport it to the soiled utility room to be cleaned and decontaminated.
- There were no smoke detectors in the training room, laboratory, store room and three offices.
- The facility failed to stock the glucometer control testing solutions used to verify the glucometer is functioning properly before use.

19 CSR 30-30.060(3)(L) Emergency drugs, oxygen and intravenous fluids shall be available in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine and endotracheal equipment shall be located in the clinical area for immediate access.

- No suction machine; and
- No endotracheal equipment.

19 CSR 30-30.060(3)(C) A medical history shall be obtained and a health assessment including a pelvic examination shall be performed. There must be confirmation of pregnancy by clinical evidence and laboratory tests. The findings shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's chart.

- The facility failed to have policies and procedures in place that addressed pelvic examinations for medication abortions.

Note: In addition to the above items, since the date of the onsite visit, the department promulgated emergency rule ***19 CSR 30-30.061, Complication Plans for Certain Drug and Chemically Induced Abortions via Abortion Facilities***. This emergency rule was effective 11/3/17. To date, your facility has not submitted a proposed Complication Plan. Since the facility's plan is to perform only medication abortions for the time being, until your facility becomes compliant with that rule, the facility cannot be licensed as an abortion facility.

Please respond in writing, providing documentation that each of these items has been fully addressed and corrected. If you have further questions, contact our office at 573-751-6083 or via email at BAC@health.mo.gov . Only upon successful completion of the revisit process can an abortion facility license be issued.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

August 18, 2009

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***August 5, 2009*** in connection with ***State Licensure*** requirements in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) working days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6303.

Sincerely,

Dean A. Linneman, MHA, MT (ASCP)
Section Director
Health Services Regulation

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	08/05/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments A licensing inspection to determine compliance with the state regulations for abortion facilities was conducted on August 5, 2009. Complaint #MO00054656 was investigated in conjunction with the licensing inspection and was determined to be unsubstantiated. Deficiencies as a result of the licensing inspection are as follows:	L 000		
L1123	19 CSR 30-30.060(1)(B)(3) The administrator shall be responsible for The administrator shall be responsible for a written plan for evacuation of patients and personnel in the event of fire, explosion or other internal disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. This regulation is not met as evidenced by: Base on record review and interview, the facility failed to assure that all staff are knowledgeable of the written fire evacuation plan by not having fire drills in accordance with facility policy. Findings include: 1. Fire drill records provided during the survey indicated that the facility has had only one fire drill per year since 2006. The fire drill records indicate drills were held on 11/09/06, 9/12/07, 6/25/08, and 7/06/09. A review of the policy "Planned Parenthood of the St. Louis Region and SW Missouri Security Protocols and Emergency Evacuation Procedures" revealed that two (2) fire drills are to be done annually. An interview with the Vice President of Patient Services at approximately 3:30 PM on 8/05/09 confirmed the findings.	L1123		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	08/05/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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L1160	Continued From page 1	L1160		
L1160	19 CSR 30-30.060(3) Patient care services shall be under Patient care services shall be under the direction of an RN. An RN shall be present in the clinical area whenever there is a patient in the procedure room or recovery room. An LPN or a surgical technician shall be present in the procedure room whenever there is a patient in the procedure room. The surgical technician shall be a certified surgical technologist or shall provide documentation of training in assisting abortion procedures. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to assure that all surgical technicians (non-licensed assistive staff present in the procedure room) provide documentation of training in assisting abortion procedures or certified surgical technologist credentials. 1. A review of the 4 personnel files of staff identified as medical assistants (non-licensed staff who assist with abortion procedures) revealed that 2 personnel files lacked any documentation of training in assisting abortion procedures or documentation of surgical technologist certification. An interview with the Vice President of Patient Services at approximately 3:30 PM confirmed this finding.	L1160		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	08/05/2009

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L1123	19 CSR 30-30.060(1)(B)(3) The administrator shall be responsible for The administrator shall be responsible for a written plan for evacuation of patients and personnel in the event of fire, explosion or other internal disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. This regulation is not met as evidenced by: Base on record review and interview, the facility failed to assure that all staff are knowledgeable of the written fire evacuation plan by not having fire drills in accordance with facility policy. Findings include: 1. Fire drill records provided during the survey indicated that the facility has had only one fire drill per year since 2006. The fire drill records indicate drills were held on 11/09/06, 9/12/07, 6/25/08, and 7/06/09. A review of the policy "Planned Parenthood of the St. Louis Region and SW Missouri Security Protocols and Emergency Evacuation Procedures" revealed that two (2) fire drills are to be done annually. An interview with the Vice President of Patient Services at approximately 3:30 PM on 8/05/09 confirmed the findings.	L1123	RHS of PPSLR will ensure that fire and evacuation drills are performed twice annually, generally one in every six month period. How and When: To rectify this in 2009, a drill will be done in October 2009 with documentation kept at the administrative office. by 10/31/09 Who: The responsibility for the drill(s) is that of the Vice President of Patient Services and the Vice President of Finance and Operations. Provisions Instituted: To prevent future deficiencies, reminders for the drills have already been entered into the 2010 calendar. This will occur for subsequent years.	

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1160	Continued From page 1	L1160	RHS of PPSLR does provide training for all surgical technicians. RHS of PPSLR will ensure documentation of such training is in the personnel records and available for review. How: The training check list for the surgical technician training will be completed, as we review with the two staff lacking it, all of the standards and responsibilities of working in the procedure room. This will then be copied for their personnel file and a copy given to each staff member. When: This will be completed within one month – by Sept 30th. by 9/30/09 Who: The Clinical Manager (NP) working with the Training and Quality Systems Coordinator will oversee the training and the documentation for this review and subsequent new hires. Provisions Instituted: All new surgical technician hires will be given a copy of the training checklist on the first day of the position. They will be assigned a qualified trainer. The training and the checklist must be completed within two weeks and before the tech can work independently. The Director of Surgical Services, who is the immediate supervisor, will ensure this is completed and sent to HR for filing in the personnel record.	
L1160	19 CSR 30-30.060(3) Patient care services shall be under Patient care services shall be under the direction of an RN. An RN shall be present in the clinical area whenever there is a patient in the procedure room or recovery room. An LPN or a surgical technician shall be present in the procedure room whenever there is a patient in the procedure room. The surgical technician shall be a certified surgical technologist or shall provide documentation of training in assisting abortion procedures. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to assure that all surgical technicians (non-licensed assistive staff present in the procedure room) provide documentation of training in assisting abortion procedures or certified surgical technologist credentials. 1. A review of the 4 personnel files of staff identified as medical assistants (non-licensed staff who assist with abortion procedures) revealed that 2 personnel files lacked any documentation of training in assisting abortion procedures or documentation of surgical technologist certification. An interview with the Vice President of Patient Services at approximately 3:30 PM confirmed this finding.	L1160		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

August 31, 2009

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Complaint survey conducted on ***August 5, 2009*** has been received in our office and forwarded to the surveyor. We want you to know the surveyor has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6303.

Sincerely,

Dean A. Linneman, MHA, MT (ASCP)
Section Director
Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

July 21, 2011

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

Case No. ***MO00071030***

Dear Mary Kogut:

This is to inform you that an off-site medical record review was conducted on your facility under the State Licensure regulations in response to a complaint we received. Based on this review, we find your facility to be in substantial compliance with CSR30.20.021 as it relates to ***MO00071030*** and no deficiencies are cited.

Please retain this letter for your files.

We welcome any questions at 573-751-6303.

Sincerely,

Kathie Thomas

Kathie Thomas MN, RN
Health Facility Nursing Consultant
Bureau of Health Services Regulation

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	C 07/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Hospitals at CSR 30-20. The complaint is unsubstantiated with no deficiencies. #MO00071030- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 12/11/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Hospitals at CSR 30-20. The complaint is unsubstantiated with no deficiencies. #MO00082026- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	C 01/07/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Hospitals at CSR 30-20. The complaint is unsubstantiated with no deficiencies. #MO00082492- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

February 20, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure & Complaint Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***January 31, 2013*** in connection with the ***State Licensure*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced allegation survey was conducted at this facility from 01/30/13 - 01/31/13. Complaint MO00082879. A state licensure inspection was conducted in conjunction with the allegation survey. The complaint (MO00082879) was found to be unsubstantiated. Deficiencies as a result of the licensing inspection are as follows:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on employee personnel file review, and review of the state statute, the facility failed to perform periodic Employee Disqualification List (EDL) checks on three of three employee personnel files reviewed. The facility does an average of 340 cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. EDL checking requirements are as follows: Section 660.315, RSMo Entities required to check the EDL: 1. Licensed as operator under Chapter 198; 2. Provides in-home services under contract with the department; 3. Temporary nurse staffing agencies;	L1111		

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L1111	Continued From page 1 4. Licensed under Chapter 197 (hospitals, ambulatory surgical centers, hospices, home health agencies); and 5. Public or private facility, day program, residential facility or specialized service operated, funded or licensed by the department of mental health. Under Section 660.315, these entities are prohibited from knowingly hiring a person, for any type of position, whose name appears on the EDL. These entities must, at a minimum, check the latest EDL (on the website after September of 2005) with updates before hiring any person for any job. 2. During an interview on 01/31/13 at 10:05 AM, Staff C, Vice President of Human Resources, stated that the facility did not do EDL checks for any of the staff currently working in the facility.	L1111		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on observation, interview, policy review,	L1128		

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L1128	Continued From page 2 and review of nationally recognized standards of practice, the facility failed to: -Ensure single use medications were discarded after use on each patient (used for multiple patients); -Ensure expired medications were available for patient use; -Date multi-dose vials when they are opened; -Ensure expired items were not available for patient use; -Ensure a sanitary environment was preserved by failure to replace worn, rusted or deteriorating equipment with functional easily cleanable surfaces that will not harbor and transmit infections in three of three Procedure Rooms; and -Ensure the facility was free of dust/debris in three of three Procedure Rooms, the storage room and supply room. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Record review of the Centers for Disease Control and Prevention (CDC) Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care, dated 05/11, showed the following: - Do not administer medications from single-dose or single-use vials, ampoules, or bags or bottles of intravenous solution to more than one patient. 2. Observation on 01/30/13 at 11:05 AM of the narcotic cabinet showed one opened 50 millimeter (ml) single dose vial of Fentanyl (pain medication) dated as opened on 01/27/13 with initials of the nurse who had opened the vial. The label on the medication stated, "single dose -	L1128		

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L1128	Continued From page 3 destroy unused contents, preservative free". 3. During an interview on 01/30/13, at the time of the observation, Staff K, Clinical Manager stated that the vials were used for more than one patient due to a shortage of the medication and the amount of waste that would result if the vial was disposed of after one use. 4. During an interview on 01/30/13 at 4:00 PM, Staff A, Vice President of Patient Services stated that the facility did not have a policy specific to single dose medication. 5. Review of the facility's policy titled, "Pharmaceutical Services", revised 12/12/12 shows: -At least monthly, supervisory staff should review the inventory to ensure that stock was being properly rotated and had not expired in all pharmaceutical storage areas; -Expired inventory must be removed from active stock. 6. Observation on 01/30/13 at 9:30 AM of emergency supplies in Procedure Room #1 showed: -One bag of Lactated Ringer (IV solution), expired 12/12. 7. During an interview on 01/30/13 at 9:45 AM, Physician D, Medical Director stated that medications and supplies were checked monthly by facility staff. 8. Observation on 01/30/13 at 10:11 AM of a cabinet in Procedure Room #2 showed: -One box of ammonia inhalant (used to prevent or treat fainting), three count, expired 05/10.	L1128		

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L1128	Continued From page 4 9. Observation on 01/30/13 at 10:45 AM of the narcotic cabinet behind the nursing station showed: -Nine vials of Valium (medication used for sedation), expired 12/01/12; -Eighteen vials of Naloxone Hydrochloride (used to counter the effects of a narcotic overdose), expired 10/12; and -Two 50% Dextrose (glucose) injectables, expired 08/12. 10. Observation on 01/30/13 at 11:10 AM of the emergency medications located in the pre-operative area showed: -One bag of Lactated Ringer expired 12/12. 11. During an interview on 01/30/13 at 11:15 AM, Staff K stated that nursing staff checked for expired medications weekly. (Note that this conflicts with Physician D's interview above, in regard to how frequently medications are checked). 12. During an interview on 01/31/13 at 10:45 AM, Staff A stated that nursing staff were responsible for checking monthly for expired medications. 13. Record review of the Centers of Disease Control and Prevention (CDC) recommendations for multi-dose vials, dated 02/09/11 showed: - When should multi-dose vials be discarded? Medication vials should always be discarded whenever sterility is compromised or questionable. In addition, the United States Pharmacopeia (USP) General Chapter 797 [16] recommends the following for multi-dose vials of sterile pharmaceuticals: - If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated	L1128		

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L1128	Continued From page 5	L1128		

and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.
The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer's original expiration date.

14. Review of the facility's policy titled, "Pharmaceutical Services", revised 12/12/12 showed:
-If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial must be dated and discarded in accordance with manufacturer's instructions and state/local regulations.

15. Observation on 01/30/13 at 9:25 AM of Procedure Room #1 showed one opened multi-dose vial of Lidocaine with no date to show when the vial was opened.

During an interview on 01/30/13, at the time of the observation, Staff L, Registered Nurse (RN) stated that she had just opened the vial that morning and she would discard it at the end of the day.

16. Review of the facility's policy titled, "Medical Equipment and Supplies", showed:
-Supplies are checked regularly by the assigned staff, rotated to ensure oldest used first, and;
-Expired supplies were removed from the active

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L1128	Continued From page 6 stock. 17. Observation on 01/30/13 at 10:35 AM of the supply room showed: -Three boxes of surgical gloves, expired 11/05; -One box of surgical gloves, expired 01/07, and; -Three postpartum balloons (used to control or reduce postpartum [occurring in the period shortly after childbirth] hemorrhage), expired 12/10, 12/11, and 01/12. 18. During an interview on 01/31/13 at 10:45 AM, Staff A stated that the policy needed to include the frequency that supplies were checked. 19. Review of the Association of Perioperative Registered Nurses (AORN) Standards and Recommended Practices, "Environmental Cleaning", dated 2012, Recommendation II showed, "A safe, clean environment should be reestablished after each surgical procedure. Routine cleaning and disinfection reduces the amount of dust, organic debris (debris in the environment) and microbial load (number and type of microorganisms contaminating an object) in the environment. Following scientifically based recommendations for cleaning and disinfection practice in health care organizations helps to reduce infections associated with contaminated items". 20. Review of the facility's policy titled, "Cleaning, Disinfection and Sterilization", revised 04/08 showed: -Thoroughly clean all surfaces that are being used in patient care areas. and; -All areas of the clinic should be kept clean and free from excess clutter. 21. Observation on 01/30/13 at 9:30 AM of	L1128		

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L1128	Continued From page 7 Procedure Room #1 showed: -One ceiling air vent that had copious amounts of visible dust/dirt; -One table with rusted castors (uncleanable surface); -One stool with rust which was covered with clear tape (uncleanable surface); -One plastic bin which contained emergency supplies was covered with dust; -One plastic bin which contained intravenous (IV/inserted into a blood vein) solution was covered with dust; and -One oxygen tank with adhesive residue (uncleanable surface). During an interview on 01/30/13 at 9:40 AM, Physician D, Medical Director acknowledged the dust on the plastic bins and stated that staff should have noticed when checking the emergency supplies. 22. Observation on 01/30/13 at 10:11 AM of Procedure Room #2 showed: -One ceiling air vent that had copious amounts of visible dust/dirt; -One IV pole with rusted castors; -One table with rusted castors; -One oxygen tank with rust and tape residue; -One suction machine with rust on the kick plates; -One plastic bin containing emergency supplies was covered with dust; and -One stool with rust which was covered with clear tape. 23. Observation on 01/30/13 at 10:25 AM of Procedure Room #3 showed: -Rust on the base of the procedure table; -One IV pole with rusted castors; -One table with rusted castors; -One oxygen tank with tape residue;	L1128		

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L1128	Continued From page 8 -One suction machine with rust on the sides; and -Two plastic bins containing emergency supplies were covered with dust. 24. Observation on 01/30/13 at 10:35 AM of the storage room showed: -One ceiling air vent with visible dust; and -The floor in the room which contained eight oxygen canisters had visible dirt and dust. 25. Observation on 01/30/13 at 10:45 AM of the supply room showed: -One suction machine with visible dust. 26. During an interview on 01/31/13 at 10:45 AM, Staff A stated that the management team was responsible for spot audits and for checking for environmental issues.	L1128		
L1170	19 CSR 30-30.060(3)(J) Each abortion facility shall develop Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following: 1. Completeness of clinical records; 2. Incidence of morbidity and mortality; 3. Intraoperative and postoperative complications; 4. All cases transferred to a hospital; 5. All cases that resulted in a length of stay of more than twelve (12) hours; 6. Errors in diagnosis;	L1170		

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L1170	Continued From page 9 7. Problems in compliance with state and local laws and regulations; and 8. All cases in which the gestational age was determined to be beyond eighteen (18) weeks. This regulation is not met as evidenced by: Based on interview and record review, the facility failed to adequately include in the Quality Assurance program all cases in which the gestational age was determined to be beyond eighteen (18) weeks. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of the facility's quarterly Quality Assurance (QA) log of complications and occurrences included the gestational age of the fetus as part of the data, but not all cases greater than 18 weeks were placed on the report. 2. During an interview on 01/30/13 at 4:45 PM, Staff A, Vice President of Patient Services confirmed that a gestational age of 18 weeks is not by itself considered a complication or occurrence, and therefore not all of those cases are routinely reviewed as part of the QA activities, only if there were also a complication and/or occurrence.	L1170		
L1171	19 CSR 30-30.060(3)(K) The quality assurance program must show The quality assurance program must show evidence of action taken as a result of the identification of the problems. This regulation is not met as evidenced by:	L1171		

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L1171	Continued From page 10 Based on interview and record review, the facility failed to adequately document action taken as a result of ongoing Quality Assurance activities. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of facility's quarterly Quality Assurance (QA) committee meeting notes indicated that while various improvement topics were discussed, there was no formal evidence presented to consistently indicate what actions were taken by the committee as a result of identification of problems. 2. During an interview on 01/30/13 at 3:50 PM Staff A, Vice President of Patient Services stated that the QA staff had many years of experience working together, knew each other well, and regularly talked about what issues were ongoing, but formal documentation of action items and the outcome could be improved. 3. During an interview on 01/30/13 at 4:25 PM, Staff G, Training and Quality Systems Coordinator stated that the facility had a corrective action tracking form that was in report format that the laboratory staff used for quality improvement, and the facility was considering using the same format for non-laboratory problems, but stated that she could not find any specific example of the form being used outside the laboratory.	L1171		
L1190	19 CSR 30-30.060(5) Complaints, Any person having a complaint Complaints. Any persons having a complaint	L1190		

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L1190	Continued From page 11 pertaining to the care of a patient rendered by an abortion facility shall direct the complaint in writing to the Missouri Department of Health, Bureau of Hospital Licensing and Certification, P.O. Box 570, Jefferson City, MO 65102. The person making the complaint shall be contacted by the Department of Health within five (5) working days of receipt of the complaint and the complaint shall be investigated by the Department of Health within twenty (20) working days of receipt of the complaint. This regulation is not met as evidenced by: Based on interview, policy review, and review of the facility's patient rights document, the facility failed to provide accurate written notice of patient rights to inform patients or their representatives of their options of who to contact to file a grievance/complaint as required. The Ambulatory Surgical Center does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of the facility's policy titled, "Client Services", revised 12/12/12 stated: -A bill of rights is available, either framed and hanging on the wall, or on the clipboards; -This specified client's rights and the facility's obligations; -For any concerns, it gives a managerial contact for clients to call; -Clients with grievances will be given to the supervisor or manager on duty; -Should this person not be available or be unable to resolve the client's issue, the client will be offered the option to talk with the next managerial level, and; -They can do this by calling that person's number	L1190		

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L1190	Continued From page 12 and extension directly or staff can take the client's name and number and forward it. 2. Review of the facility's "Bill of Rights" that patients are given prior to a procedure, gave direction for the patient to contact the Health Center Coordinator or the Director of Surgical Services, and provided the facility telephone number. (Note that the notice of rights failed to state that patients could report their complaint to the state agency, failed to include the state agency address, and telephone number). 3. During an interview on 01/31/13 at 11:00 AM, Staff A, Vice President of Patient Services stated that the facility had not been including/providing the state agency information (address and telephone number) in the "Bill of Rights" document that was presented to patients.	L1190		
L1252	19 CSR 30-30.070(3)(L) At least two (2) ABC-type fire extinguishers At least two (2) ABC-type fire extinguishers shall be located in the facility, one (1) in the clinical area; This regulation is not met as evidenced by: Based on observation and interview, the facility failed to conduct a monthly inspection of the portable fire extinguishers. This deficient practice affects all occupants in the facility. The facility does an average of 340cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. Observation during a tour of the facility	L1252		

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L1252	Continued From page 13 conducted on the morning of 01/30/13, showed the monthly inspection tags on all of the portable fire extinguishers were blank indicating a monthly inspection had not been conducted. 2. During an interview on 01/30/13 at 2:20 PM, Staff A, Director of Patient Services stated the facility staff did not conduct monthly inspections of the portable fire extinguishers.	L1252		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced allegation survey was conducted at this facility from 01/30/13 - 01/31/13. Complaint MO00082879. A state licensure inspection was conducted in conjunction with the allegation survey. The complaint (MO00082879) was found to be unsubstantiated. Deficiencies as a result of the licensing inspection are as follows:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on employee personnel file review, and review of the state statute, the facility failed to perform periodic Employee Disqualification List (EDL) checks on three of three employee personnel files reviewed. The facility does an average of 340 cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. EDL checking requirements are as follows: Section 660.315, RSMo Entities required to check the EDL: 1. Licensed as operator under Chapter 198; 2. Provides in-home services under contract with the department; 3. Temporary nurse staffing agencies;	L1111		

	STATE OF MISSOURI PLAN OF CORRECTION	
Provider/Supplier Name:	Reproductive Health Services / Planned Parenthood St. Louis Region & SW MO	Survey Date
STREET ADDRESS, CITY, ZIP:	4251 Forest Park Ave, St. Louis MO 63108	1/30 - 1/31/13
	(X1) PROVIDER/SUPPLIER/CLIA INDENTIFICATION NUMBER 17-	26D0438374

The Administrator signing and dating the first page of the CMS-2567/State Form is indicating their approval of the plan of correction being submitted on this form.

(X4) ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
L1111	A new human resource policy has been initiated to ensure that all RHS staff, prior to hiring, will be checked through the EDL data base. RHS of PPSLR will not hire a person on this list. In addition the existing, current staff will be checked against the EDL. (RHS of PPSLR has already registered under the MO State Dept of SS and is awaiting and log ins)	
	Attached: New Policy	
	Person Responsible: VP of Human Resources	3.15.13
	Monitoring and Incorporation into QAPI process: a report of activity will be forwarded to VP of Patient Services for incorporation into meeting minutes	Starting w/April '13 meeting
L1128	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure single use medications are discarded after use on each patient	
	Attached: New Policy, Page 7	
	Person Responsible: VP of Patient Services	2.27.13
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff.	2.27.13
	Person Responsible: Director of Surgical Services, Clinical Manager	
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator will spot check this weekly for the first month and then monthly. A consolidated report on all Infection Control activities will be shared with the VP of Pt Services and at the CQA meeting	First checks wk of 3/4 and continuing
	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure the multi-dose vials are appropriately dated when they are opened	2.27.13
	Attached: New Policy, Page 7	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	2.27.13
	Person Responsible: Director of Surgical Services, Clinical Manager	

David L. Eisenberg, MD, MPH

Medical Director
Title

2-27-13
Date

	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator will spot check this weekly for the first month and then monthly. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the CQA meeting	First checks wk of 3/4 and continuing
	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure that expired medications are not available for patient use. The revision clarifies dates on which supplies are checked (i.e. the first working clinic session of every month).	2.27.13
	Person Responsible: VP of Patient Services	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	
	Attached: policy, page 3	
	Person Responsible: Director of Surgical Services, Clinical Manager	2.27.13
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator or a delegate from the infection control committee will spot check this weekly for the first month and then monthly. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the CQA meeting	first full week of every month
	The General Standards section of the policy and procedure manual has been revised to ensure that expired items are not available for patient use. The policy is more specific on when items are checked and how discarded	2.27.13
	Person Responsible: VP of Patient Services	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	2.27.13
	Attached: new policy, pages 26 and 27	
	Person Responsible: Director of Surgical Services, Clinical Manager	
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator or a delegate of the Infection Control Committee will check this in the first week of the month. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the quarterly CQA meeting.	first full week of every month
	To ensure that a sanitary environment is preserved several actions have been taken and are to be taken:	
	1) new footstools have been purchased and the old discarded	2.15.13
	2) bids have been sought for new berkeleys and new IV poles	2.13 & 2.25.13
	3) the maintenance and cleaning crews are using cleaning products to determine if our surfaces are easily cleanable or need replacing	2.13 - 2.28.13
	4) for items that must be purchased, this will occur	3.15.13
	Person Responsible: VP of Patient Services and VP of Finance/Operations	
	5) ongoing monitoring of equipment, cleanable surfaces, and their condition	
	Person Responsible: procedure room staff and Infection Control Committee	
	Staff Training: Training and Quality Systems Coordinator and Clinical Manager	3.1.13

	Monitoring: ongoing monthly auditing and checking of equipment and cleanable surfaces. Recommendations for improvements to VP team as indicated. Audits will be shared at CQA quarterly meetings	Monthly starting in March '13. Reports quarterly
	To ensure the facility is free of dust/debris throughout the medical area, including procedure rooms, storage and supply room:	
	1) the air ducts in the procedure rooms and recovery have been cleaned	2.5.13
	2) the maintenance dept will check them monthly and clean them as necessary	3.5.13 ongoing
	3) a new cleaning schedule has been put into effect - procedure room and utility staff clean their rooms every Tuesday prior to the start of clinic	2.15.13
	4) the cleaning staff will provide heavy cleaning of the entire clinical area every Monday and Thursday	
	5) Medical Assistants will rotate responsibility for storage and shared areas	
	6) a check list is being designed to ensure all items are addressed	2.27.13
	Staff Responsible for Cleaning: Medical Assistants and Housekeeping	
	Staff Responsible for Monitoring: Management (rotating) and Infection Control Committee	
	Timeline for monitoring: weekly checks for first month, then monthly	Tuesdays
	The Infection Control Committee, which was founded in November 2012, invited staff members to join and will be responsible for: updating the manual, designing audits, monitoring outcomes, recommending training, setting standards, ensuring incorporation of changes into QAPI, and reporting to the Clinical Quality Assurance Committee. All of the above will be monitored by them as well as by those stated above.	first meeting week of 3/4/13
	Staff Responsible: Training and Quality Systems Coordinator as manager of the committee	
	Staff Training: For above issues, already stated. For new topics, training will be as indicated and decided upon by committee	
	Monitoring and incorporation into QAPI process: reports to the Clinical Quality Assurance Committee and Medical Director	quarterly reports
L1170	The Quality Assurance Program will be improved via the following actions:	
	1) the agenda will be more specific regarding all of the issues identified by regulations	2.6.13
	2) the review of patient records will include a new log of all cases in which gestational age is 18 weeks or greater and will show a review by a physician (i.e. the Medical Director)	3.1.13
L1171	3) the notes will identify each problem and the accompanying action to be taken to resolve the problem	2.6.13
	4) successive notes will address the action taken and the outcome	Next QA meeting in April 2013
	5) further action will then be addressed as indicated	

	Staff Responsible: VP of Patient Services, Medical Director, and Training and Quality Systems Coordinator	
	Committee Training and Preparedness: was discussed at the 2.6.13 meeting. Follow up with individual members week of 2.25.13 to ensure actions as decided	
L1190	The patient Bill of Rights has been updated with the addition of the address and phone number of the MO Department of Health and Senior Services, Bureau of Ambulatory Care. It is made assessible to patients by being attached clipboards that are given to every patient with their initial paperwork.	2.1.13
	Attached: new bill of rights	
	Staff Responsible: VP of Patient Services	
L1252	PPSLRSWMO pays to have annual inspections of the fire extinguishers. In addition, the maintenance staff will now do a monthly inspection of the fire extinguishers to ensure the pressure is correct, they are in working condition, and there is no blockage.	first week of March 3/4/13
	Staff Responsible: Maintenance	
	Training: none required	
	Monitoring to ensure POA is effective: will be checked for three months by VP of Finance/Operations and then spot checked over the next year	once in March, April, May, then periodically

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CLINICAL PROGRAM STRUCTURE
GENERAL STANDARDS
PAGE 26 AND 27
(entire document not sent)

VIII. MEDICAL EQUIPMENT AND SUPPLIES

Medical Equipment and Supplies must —

A. Be appropriate and adequate to provide the services offered. All centers have microscopes, refrigerators, autoclaves, venipuncture and injection supplies, scales, sphygmomanometer, and appropriate gynecologic equipment.

B. Equipment is checked and calibrated annually by a contract service for safety, and written documentation is kept on file at the administrative office.

L1128

A. Equipment is also checked by staff and managers monthly according to the infection control policy

- **a. Check for rust, cleanliness, tape, or any uncleanable surface**
- **b. Worn or defective equipment must be reported to the manager for replacement or fixing by the staff who identified this**

D. Supplies are checked regularly and at least monthly by the assigned staff. The person checking will vary per center and is delegated by the manager of the center.

a. For RHS, staff are the medical assistants assigned to procedure rooms and to storage areas

b. For RHS, the LPN/RN will check the recovery and storage there

c. For HCs, the support staff (MA / Patient Educator) will check the exam rooms, labs, storage area

d. Supplies are rotated to ensure oldest used first

e. Expired supplies must be removed from the active stock and not used for patient care

f. Supplies are checked on the first clinic day of each month

g. Managers and the Infection Control Committee will be providing spot checks periodically

E. See specific sections for additional supply and equipment for that service.

F. Facility Cleaning Standard
As a medical facility, PPSLR/SWMO must maintain sanitary environments for patient

Care. To ensure this:

- **a. Some centers have a contractual agreement with a cleaning service that does heavier cleaning 3 x weekly**
- **b. In the interim between their visits, staff are**

responsible to empty trash, wipe down any spills, disinfect areas that have become contaminated or dirty

c. **Some centers have their own cleaning crew who may perform the heavier cleaning of mopping, baseboards, vacuuming, etc – this must be done according to volume of traffic and may be 2 – 3 times weekly**
d. **At RHS, the procedure rooms, recovery, and storage are closely monitored and cleaned at least once per week – every Monday for the heavier cleaning and every Tuesday before clinic session for dusting and debris management**
e. **The monthly Infection Control audit will check that a sanitary environment has been achieved for patient care**

For additional information, please see the Infection Control Manual and audits

IX. INFECTION PREVENTION/CONTROL

All affiliates **must** have an infection prevention program in place. The ARMS *Infection Prevention Manual* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs. .

PPSLR/SWMO manual uses the ARMS one as the basis and provides both policy and procedural information. An Infection Prevention Committee has been established through the Patient Services Department and consists of nursing, administrative, and clinical support staff. Their purpose is surveillance, investigation, control and prevention of infection. This will be accomplished by review, revision, and approval of infection prevention policy and procedures.

X. RISK AND QUALITY MANAGEMENT

L1170 and L1171

PPSLR/SWMO and its affiliate RHS of PPSLR/SWMO have a structured and permanent Risk and Quality Management Program in place. The ARMS *manual Risk Management: The Path to Patient Safety* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs. The affiliate's Quality Management Program includes the following:

1) A CQRM Committee chaired by the Training and Quality System Coordinator and membership of: CEO; VPs from all departments (Patient Services; Political; Education and Diversity; Administration and HR; Finance and Operations; Development), Medical Director, and Board member.
Committee is responsible for agency oversight for QM/RM activities and concerns such as security, technology, personnel issues. The committee is responsible for overseeing goals and identifying processes to evaluate. This is accomplished by the following:

- Review of reporting agency departmental and committee audit findings to identify and explore possible risk and exposure areas
- Develop protocols/procedures as needed to reduce the risk of exposure to loss

- Inclusion of risk management concepts in the annual Quality Management Plan
- Participate in the annual review of the PPFA QM & RM Self-Assessment Survey Review to ensure PPSLR in compliance with standards and guidelines for accrediting agencies such as Planned Parenthood Federation of America, Title X and Medicaid
- Committee members serve in an over-sight capacity for monitoring and improving PPSLR/SWMO facility management in the areas of safety and security for clients, visitors, staff and volunteers

Page 29 addition regarding CQAC

The following agency committees report to the QM committee:
Clinical Quality Assurance Committee for Patient Services (all divisions)

Due to state licensing, the CQAC must address the following issues – this will be done through a detailed agenda, discussion, notes, and analysis of the outcomes of the decided upon actions.

From state regulations:
(J) Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following:

1. ***Completeness of clinical records;***
2. ***Incidence of morbidity and mortality;***
3. ***Intraoperative and postoperative complications;***
4. ***All cases transferred to a hospital'***
5. ***All cases that resulted in a length of stay of more than twelve (12) hours;***
6. ***Errors in diagnosis;***
7. ***Problems in compliance with state and local laws and regulations;***
8. ***All cases in which the gestational age was determined to be beyond eighteen (18) weeks.***

(K) The quality assurance program must show evidence of action taken as a result of the identification of the problems.

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Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri

Infection Prevention Compliance Audit
Sterilization Practices

	Met	Unmet	Improvement Plan/Date to be Completed
1 All medical equipment (i.e. speculums, medical instruments, etc.) are immediately placed in appropriate disinfectant solution after use			
2 Staff can verbalize above disinfectant solution ratio			
3 Proper PPE is worn by staff during cleaning process (utility gloves with instrument cleaning in utility)			
4 Instruments are not allowed to dry before cleaning procedure			
5 Documentation exists for high level solution check for each use			
6 Equipment sterilized in the autoclave contains an indicator for sterilization within each package			
7 No package wrapped for steam sterilization is more than 12x20x12 inches in size			
8 Documentation of weekly steam sterilizer cleaning and spore testing			
9 Supplies of sterile instruments are stored no less than 8-10 inches from the floor and 18-20 inches from the ceiling			
10 Sterile supplies are checked monthly for integrity of the pack			
11 All sterile items are labeled with the date of sterilization and specific autoclave			
12 No expired merchandise or supplies on shelves in active stock			
13 Multi-use vials dated & initialed when opened and discarded according to regulations			
14 Single use medications are used for one patient and discarded after use			
15 All exam tables are wiped with disinfectant after each procedure			
16 Sterilize and non-sterile items are stored separately			
17 All equipment is sterilized in "open" position			
18 Sterile supplies are rotated to ensure use of most recently sterilized equipment last			
19 Antimicrobial hand rinse available			
20 No biohazard in white bag trash			
21 Sharp containers easily accessible (in lab, exam, utility, procedure and recovery areas)			
22 PPE available (masks, protective eyewear, utility gloves, plastic apron, etc)			
23 Vaginal probes are disinfected between each patient			
24 Condoms are used to cover vaginal ultrasound probe			
25 Tubing labeled by manufacturer as single use tubing is disposed of infectious waste after a single use.			
26 Multi-use suction tubing is cleaned, then disinfected as for a semi-critical item			
27 Abortion procedure bottles are changed, cleaned and disinfected between patients			
28 MVA is completely disassembled, cleaned and receive high-level disinfection			
29 If Cidex used, must be checked and documented on day of use to ensure effectiveness			
30 MSDS log current with supplies used in surgical center			

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Auditor Name:_____Title_____ Date_____

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L1128

Signature & Title of reviewer:_____

Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri

Infection Prevention Compliance Audit
Standard Precautions, Hand Hygiene and PPE

	Met	Unmet	Improvement Plan/Date to be Completed
1 Sharp containers are leak proof, puncture resistant, labeled with biohazard label, sealed and disposed of when they are no more than ¾ full and sealed completely before disposal			
2 All sharps are disposed of in designated sharps containers (include hypodermic, intravenous or other medical needles, syringes with an attached needle or other sharps, scalpel blades, blood vials, slides & cover slips, syringes that have come in contact with blood or infectious agents, etc.)			
3 Employees demonstrate proper hand washing or disinfecting technique before putting gloves on /removal of gloves and before each patient encounter.			
4 Eye protection/face shields are used when activity holds possibility of splash			
5 Safety needles are used when available; includes needle devices containing built-in safety features			
6 When sterile gloves are used, proper technique is followed for putting on and removal			
7 Appropriate PPE (i.e. various gloves, masks, face shield, lab coats, CPR shield) is readily available in each area of health center (lab, procedure, utility rooms, etc)			
8 Gloves are worn by staff when contact with blood, OPIM, mucous membranes and non-intact skin may occur			
9 Gloves are worn when giving injections, drawing blood and performing Venipuncture			
10 Red bags are used for non-sharps, regulated medical waste (i.e. products of blood & anything caked, soaked or dripping with blood; saturated materials containing blood)			
10 PPE is disposed of in proper container (red bags if contaminated)			
11 Every hand washing station contains soap, hand disinfectant and towels available for proper hand hygiene			
12 Surgical scrub is employed for hand hygiene by physician/clinician before clinic surgical session and waterless alcohol foam product used between patients			
13 Sterile packages are used that have outside tape that indicates the package has been processed			
14 Non-sterile persons avoid reaching over a sterile field; sterile persons avoid leaning over a non-sterile area			
15 When sterile packs are opened, the outside of the package never touches the inside			
16 Routine schedule and guidelines for housekeeping & cleaning is followed			
17 Patient care equipment is free from dust and debris in procedure, storage and supply areas			
18 Environmental surfaces are thoroughly cleaned/disinfected in patient care areas between patients			
19 Staff can verbalize guidelines for cleaning/disinfecting after a blood/body fluid spill			
20 Emergency Surgical Cart free from dust & debris			

L1128

Auditor Name:_____ Title:_____ Date:_____

Signature &Title of reviewer:_____

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L1128

Staff Training
2.27.13

Trainers:
Lead Clinician Susan Bender, NP
Director of Surgical Services Celeste Smith, LCSW

I. Time for a change
   a. What are some things you think we need to change?
   b. What gets in the way of us being excellent?
   c. What can we start doing differently?
II. Single Use Medication Vials for One Patient
III. Multi-Dose Medication Containers are Labeled with Date Opened
IV. Labeling Pre-Drawn Medications
   a. Date
   b. Time
   c. Initials of Staff Drawing Up Meds
V. Expired Medications
   a. Plan to check the last working day of each month
VI. Expired Supplies
   a. Plan to check the last working day of each month
VII. Clean and Sanitary Environment
   a. Environment Includes
      i. Dressing Room
      ii. Recovery Room
      iii. Procedure Rooms
      iv. Utility
      v. Supply Areas
      vi. Storage Areas
      vii. Hallways
      viii. Floors
      ix. Ceilings
   b. Targeted clean each Monday/Tuesday Morning
      i. Dust
      ii. Debris
      iii. Clutter
      iv. Appearance Matters
      v. Day to Day Upkeep
      vi. Leave your workstation clean
   c. Un-cleanable Surfaces
      i. What are they?
      ii. How do we fix them?
      iii. How do Monitoring them?
VIII. Infection Prevention Committee
   a. What is it?
   b. Who is on it?
   c. How can it help us?
IX. Questions?

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AS A PATIENT OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION AND SOUTHWEST MISSOURI, YOU HAVE THE FOLLOWING RIGHTS:

The RIGHT to no discrimination regardless of race, color, national origin, disability, age, ethnicity, sexual orientation, financial ability, education level, marital status, religion, number of pregnancies, method of referral, contraceptive preference or other factor;

The RIGHT to be treated with dignity and respect without harassment;

The RIGHT to decide whether or not to bear children and if so, to determine the timing and spacing;

The RIGHT to privacy and confidentiality in all aspects of the service we provide;

The RIGHT to know of the effectiveness, possible side effects, and complications of all contraceptives;

The RIGHT to participate in selecting the contraceptive methods to be used;

The RIGHT to know the results and the meaning of all tests and examinations;

The RIGHT to access your records and have them explained;

The RIGHT to know the meaning and implication of all forms we ask you to sign;

The RIGHT to consent to or refuse any contraceptive method, test, examination or treatment;

The RIGHT to an explanation of fees and services before services are provided.

- You will not be denied access to services if unable to pay
- We accept Medicaid and Medicare
- We accept commercial health insurance
- Please discuss any special concerns with our staff

If any problems should arise during your visit, please ask to speak to the Health Center Coordinator or contact the Director of Surgical Services at 314-531-7526 ext. 231.

Planned Parenthood

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You may also contact the State of Missouri Department of Health and Senior Services, Bureau of Ambulatory Care. PO Box 570, Jefferson City, MO 65102. Telephone: 573 751-6083.

L1111

BACKGROUND CHECKS AND INVESTIGATIONS POLICY

PPSLRSWMO recognizes the importance of maintaining a safe and productive workplace with honest, trustworthy, qualified, reliable and non-violent employees. For the benefit of all employees and PPSLRSWMO, in furthering these interests and enforcing PPSLRSWMO policies, PPSLRSWMO **will** perform, or request that third parties perform, "background checks" or other types of investigations. These background checks and investigations may be performed by PPSLRSWMO at its discretion. **The Vice President of Human Resources will be responsible for performing all "background checks" that are applicable under Federal, State and Planned Parenthood of America (PPFA) laws and requirements.**

Background checks and investigations performed for PPSLRSWMO may include the use of consumer reporting agencies which may gather and report information to PPSLRSWMO in the form of consumer or investigative consumer reports. Such reports, if obtained, may contain, but are not limited to, information concerning an applicant's or employee's credit standing or worthiness, credit capacity, character or general reputation. The types of reports that may be requested from consumer reporting agencies under this policy include, but are not limited to, credit reports, criminal records checks, driving records, and/or summaries of educational and employment records and histories. The information contained in these reports may be obtained by a consumer reporting agency from private or public records sources or through personal interviews with an employee's co-workers, neighbors, friends, associates, current or former employers or other personal acquaintances.

Pursuant to this policy, PPSLRSWMO may request consumer reports, including records checks and investigative reports based on interviews, in connection with an individual's application for employment, or at any time during the course of an employee's employment with PPSLRSWMO, for purposes of evaluating their suitability for employment, promotion, reassignment or retention as an employee.

All PPSLRSWMO Reproductive Health Services (RHS) candidates prior to hire will have a criminal background check and Employee Disqualification List (EDL) search completed prior to hire per the Missouri Revised Statutes Chapter 660 section 317.

Employees are expected to cooperate fully with the background checks and investigations policy. Such cooperation includes, among other things, providing truthful and complete information in response to inquiries made by PPSLRSWMO or third party investigations during the course of investigations and providing appropriate written authorizations that may be required by law so that

PPSLRSWMO may obtain complete investigation reports. Failure to cooperate in these checks or investigations, or any attempt to interfere with PPSLRSWMO attempts to obtain information, may result in disciplinary action, up to, and including, termination.

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L1128
PHARMACEUTICAL SERVICES
See pages 3 and 7

I. PHARMACEUTICAL SERVICES

Affiliate Staff

1. **Medical Director** — is responsible for developing policies and procedures for pharmaceuticals that **must** include
   - formulary of all drugs stocked in the affiliate that is reviewed annually
     i. Consider the potential for medication errors when developing formulary. Look-alike, sound-alike drugs should be identified as being at "high risk" for potential error. Extra steps should be taken to ensure safety.
   - list of additional therapeutic/pharmacologic classifications of drugs that may be ordered for clients to obtain at outside pharmacies
     - The formulary is approved annually with medical protocol updates
     - All drugs, devices, and medications stocked in the affiliate are approved by the Medical Director in advance of purchasing / acquiring and providing.
     - The Medical Director only approves drugs that are FDA approved and only from manufacturers certified by the FDA, unless the medication is part of a research study.
     - All research study medications must be approved by the IRB and Medical Director prior to use.
     - PPSLR has both an internal (for items stocked in-house) and external formulary (inclusive of in-house and by written/e-prescription).
     - RHS has a formulary specific to abortion care approved by the Medical Director.
     - The Medical Director, Lead Clinician, and VP of Patient Services review the formularies at least annually. The Medical Director approves and signs off on the formulary of both departments.
     - RHS has a formulary. The surgical physicians have discretion to provide other medications as needed.
   - provision of pharmaceuticals in accordance with all state/local laws and regulations
     - PPSLR/SWMO and RHS of PPSLR/SWMO pharmaceuticals are provided by physicians, by clinicians or by physician designee.
     - APNs work under collaborative practice agreements with the PPSLR Medical Director and Associate Medical Directors. They have prescriptive and dispensing privileges.
     - RNs/LPNs work under standing orders with the PPSLR Medical Director.
     - Physicians have the ability to prescribe as indicated for patient care.
   - a drug control system that covers the interval from the time pharmaceuticals are ordered until they are provided to the client
     - PPSLR/SWMO's system includes the interval from issuing a request for order from health and surgical centers to the purchasing clerk, to ordering them from the pharmaceutical companies, to delivery and storage, to client provision.
   - inspection of all drug storage areas to remove expired drugs
   - designation of which staff may have access to bulk storage areas
   - management of pharmaceutical product irregularities and drug and device recalls
2. There **must** be documentation that in-service education pertaining to the nature

and safety aspects of pharmaceuticals is provided to staff involved in the preparation and provision of medications.

- PPSLR/SWMO provides an annual training for staff, primarily clinicians and licensed providers

FYI — Look-alike, Sound-alike (LASA) Medications

Confused drug names are one of the most common causes of medication error. With tens of thousands of drugs currently on the market, the potential for error due to confused drug names is significant and exists worldwide. Contributing to the risk of confusion are illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labeling, similar clinical use, similar strengths, dosage forms, frequency of administration, and the failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct rigorous risk assessments, both for nonproprietary and brand names, prior to approving new product names.

Go to the Institute of Safe Medication Practices for a list of LASA medications. The list includes those medications that are known to have been involved in medication errors, as well as the Joint Commission's list of LASAs.

(WHO 2007); (ISMP 2010)

Procurement

1. There **must** be a written order for all drugs/pharmaceuticals/chemicals brought into the affiliate.
   - A copy of the purchase order or the prescription **must** be kept in the affiliate's files. A signed receipt **must** be obtained for pharmaceuticals shipped from a central location to outlying centers or clinics. If the delivery is made by affiliate staff, a signed receipt is not necessary.
     - The original order is issued by the supervisory staff of the health center or surgical center;
     - The order is sent to the Payroll/Purchasing Clerk via internal e-mail or fax;
     - Each facility has its own account number with each supply or pharmaceutical company;
     - The order is placed by the purchasing clerk at the administrative office;
     - Most deliveries are sent directly to the service location from the company;
     - Specific items are shipped centrally to control pricing;
     - Upon delivery, products are checked for accuracy and security, the packing slip is dated and initialed;
     - A copy of the purchase order or the prescription is and must be kept in the affiliate's files.
     - For items shipped to a central location, supervisory staff is responsible for picking up the supplies and completing a form that is sent to purchasing detailing amount and to which budget to allocate costs.
     - Finance maintains all purchase orders, packing slips, invoices, and paid statements for all pharmaceuticals.
   - Controlled substance order and receipt records **must** be filed separately from

the other pharmaceutical purchase records. RHS is the only facility that orders controlled substances.

2. If pharmaceuticals are routinely purchased from a community or hospital pharmacy and if the items are not supplied in manufacturer original containers, there should be a written contract specifying, as a minimum, requirements for labeling. PPSLR/SWMO seldom, if ever, purchases, pharmaceuticals from other than manufacturers. An exception is the free meds provided by the states of MO and of IL for the IPP programs.
3. If available, pharmaceuticals should be purchased in manufacturer prepared unit-of-use packages.
    - An exception is limited STD medications provided free to the health centers from the Illinois Department of Health and the MO Department of Health and limited medications for RHS. In these cases repackaging standards in this section are followed.
4. Only drugs and devices approved by the Federal Food and Drug Administration (FDA), and manufactured for sale in the United States may be used. Affiliates may not import drugs and/or medical devices from other countries for use in their health centers.
5. For any additional drugs that must be prescribed and are not purchased, the "out-of-house" formulary is utilized.

Storage

1. Access to stored pharmaceuticals
    a. The bulk storage area **must** be secure. The clinician or nurse on duty has the key in her possession to enable easy provision to clients. Other staff may have access via the clinician. Limited supplies are accessible to clinic staff working the receptionist desks.
    b. Controlled substances **must** be under double lock and in a secure area at all times. RHS is the only facility with controlled substances and follows MO law regarding storage of the drugs.
    c. Access to pharmaceuticals dispensed from within client care areas should be limited to health care providers responsible for dispensing these items.

L1128

2. **Pharmaceuticals in all storage areas**
    a. Arrange medications so that the oldest stock is used first
        i. On the first clinic session of each month, a delegated staff reviews the inventory to ensure that stock is being properly rotated and has not expired
        ii. Expired inventory must be removed from active stock and marked as expired to ensure it is not available to patient care. It will be returned or discarded according to the vendor or manufacturer's instruction.
        iii. The senior management team, during routine audits, will also check the inventory for proper stock rotation.
    b. Do not store look-alike, sound-alike medications alphabetically. Store them out of order or in a separate location (The Joint Commission 2001)
    c. Pharmaceuticals meant for internal use **must** be stored separately (i.e. on a separate shelf) from those for external (i.e. topical) use only. Clear and highly visible labeling is required.
3. Other PPSLR/SWMO policies related to storage
    a. Inventory levels for pharmaceuticals that are not high volume should not exceed six-month stock.
    b. All pharmaceuticals, contraceptives, and therapeutics will be stored

according to the manufacturers' suggestions to ensure preservation (i.e. refrigeration, limited access to light exposure, etc).

c. An inventory check is performed monthly by supervisory staff to ensure accurate counts and to limit misappropriated medications and supplies.
d. Expired pharmaceuticals should be disposed of by throwing them into the biohazard box, sending them back to manufacturer, or taking them to appropriate and identified pharmacies that PPSLR/SWMO has approved for disposal (see VP of Patient Services or Clinical Manager). (Varies with product) Some items may be used for demonstration and educational purposes. Expired items must be accounted for on the Monthly Inventory Form and deleted from the inventory as soon as discovered to be expired.
e. The supervisory staff of all centers is responsible for discarding pharmaceuticals appropriately. The Purchasing Clerk will contact the manufacturer to determine if a rebate on expired products exists.
f. For any centralized inventory the Purchasing Clerk will remove it from the shelves.
g. No client will be dispensed a drug with an expired date.
h. Controlled substances must be destroyed by two nurses and documented on the Controlled Substance Dispensing or Administration Log Sheet. (see below for more policies/procedures on controlled substances)

4. At the end of each fiscal year, a full manual inventory is performed in each site.

Repackaging — i.e., the preparation of multiple containers of dispensing size from a bulk container (for example, repackaging a bottle of 1000 tetracycline tablets into vials of 20 tablets each). Repackaged vials are stored and dispensed to clients as needed.

1. Repackaging **must** be done in accordance with state/local laws/regulations. For PPSLR/SWMO and affiliates this is under the supervision of a physician who is on the premises at the time of repackaging.

2. A log **must** be maintained to document the supervision (by signature), the person doing the repackaging (by signature) and the identification of the bulk drug being repackaged. Logs **must** be archived according to state/local laws/regulations. The log should contain the following information:
   - complete product description — name, strength, manufacturer
   - the manufacturer's lot number
   - an expiration date, no later than the manufacturer's expiration date of a not previously opened manufacturer's container.
   - a control number or some other unique (code) identification that will link that manufacturer and drug lot with the repackaged units

3. All repackaged units **must** have a standard label affixed to each package (bottle, etc.) before they are entered into active stock. The label **must** include at least the following:
   - name and address of the affiliate
   - name of the drug and quantity
   - strength of the drug when appropriate
   - The expiration date, for drugs repackaged in "tight" containers such as plastic vials or glass bottles.
     - This should be the date specified on the original manufacturer's container, or one year from the date the product was repackaged, whichever is earlier.
     - The expiration date for drugs that are repackaged from unit dose

containers should be no greater than 60 days from the date of repackaging, or the manufacturer's expiration date on the original container, whichever is earlier.
  - State laws may be applicable to expiration date for repackaged pharmaceuticals.
- the control number linking that unit with the manufacturer's product drug lot — for example, a code showing the month and day of repackaging and number repackaged that day (as below, where 01=month, 21=day of repackaging, and 04=fourth item repackaged that day)

Sample label for drugs repackaged in tight containers:

Planned Parenthood of St. Louis Region 888 Main St., City, State, ZIP
Acetaminophen Tablets 325 mg, Qty. 25 Exp. 12/81, Control #012104

4. Safety precautions should be taken to indicate if the original repackaging unit has been opened prior to this dispensing, e.g., such as putting latex seals over the cap of the original vial after carrying out repackaging. An "x" could also be marked on the bottle cap or label to indicate it has been opened.

Compounding
PPSLR is not involved in the compounding of any medications in any of its facilities.

Labeling Prescription Vials for Clients
1. Prescription labels should be designed to enhance client safety. Click here (http://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp) to access recommendations from the Institute for Safe Medication Practices.
2. All prescription vials **must** have a permanently adhering label affixed directly to the container with at least the following information (currently provided by wholesaler):
   - name and address of the affiliate — The acronym, PPSLR/SWMO, may be used
   - name, strength, quantity dispensed of the drug
   - expiration date
   - lot number

   The label **must** also include the following information, which may be added by hand at the time of dispensing
   - date of the prescription
   - name of the client
   - directions for use including frequency and route of administration
   - name of the prescriber
   - number of refills, if applicable

   Sample label for prescription vial for client

Planned Parenthood of the St. Louis Region 888 Main St., City, State, ZIP
{date}

{client name} Take ____ tablets every ____ hours as needed for pain. {Dr. _____}
Acetaminophen Tablets 325 mg, Qty. 25 # refills Exp. 12/81, Control #012104

3. Auxiliary labels should be used to provide other information to the client, such as, "Do not drink alcohol." in the case of metronidazole. The label(s) that should appear on the prescription container can be found in the literature about each drug including the manufacturer's package insert. The labels come with the medications from the supplier and should be attached to the vial upon dispensing. PPSLR/SWMO standardizes the use of auxillary labels for consistency.

4. The plastic case or other container for oral contraceptives **must** bear the full label and include the FDA package insert. The refill units given at the same time need not be individually labeled. If the original case or container is not presented for subsequent refills, then the refill units can be put into a bag and the outside of the bag labeled.

Containers

1. Coin envelopes **must not** be used to dispense solid dose pharmaceuticals, since these do not meet the requirements of the Poison Prevention Packaging Act, a 1970 amendment to the Federal Food, Drug and Cosmetic Act requiring child-proof containers for pharmaceuticals. Self-contained packages, such as oral contraceptives or intravaginal creams, are exempted. PPSLR/SWMO does not use coin envelopes for any purpose.

2. All prescription medications should be stored in containers that protect them from light.

Controlled Substances

1. All controlled substances dispensed for out-patient use **must** bear the federally mandated auxiliary label: "Caution. Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

2. A daily count at the beginning and at the end of the clinic day **must** be taken on days when controlled substances are administered or prescribed. Discrepancies **must** be immediately reported to the supervisor, and recorded in the controlled substances inventory:
   - two countersignatures are required at the time of the count
     or
   - one person signing the daily count, and two persons taking and signing a full count every thirty days
     or
   - as required by state law
     1. RHS has two nurses (LPNs or RNs) doing the count
     2. Staff record on the Controlled Substance Dispensing or Administration Log: date of count, lot number of drug, first initial last name and title of counting nurses.
     3. If the nurses who count recognize that the levels of the medication have fallen below the designated levels, they will notify the supervisory for reordering.

a. Fentanyl: ordered when it falls to 6 vials
b. Versed: ordered when it falls to 40 vials
c. Diazepam: ordered when it falls to 400

4. Approximately one month's supply of controlled substances will be kept in stock at all times to prevent the clinic from running out of stock. In cases where a national shortage is expected, more inventory will be approved by the manager

3. All inventory and purchase records for controlled substances **must** remain on file for the duration specified in state law if greater than the federal standard of five years. PPSLR/SWMO and its affiliate RHS maintains them for a minimum of seven years.

4. All Level IV controlled substances must be ordered and signed by the Vice President of Patient Services or the Clinical Manager (an APRN).

Other

L1128

1. **Single use medications are used for one client only and are discarded after use on each patient.**
   a. **Staff must follow manufacturer's labeling on how to use the medication**
   b. **The medication is discarded according to the manufacturer**
2. **Manufacturers' recommendations for storage of opened and unopened multi-dose vials must be followed.**
   a. **When a multi-dose vial is used, appropriate infection prevention procedures to prevent contamination should be employed. (CDC 2011)**
   b. **Vials must be discarded if there is evidence of contamination.**
   c. **If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial must be dated and discarded in accordance with manufacturer's instructions and state/local regulations**
      i. **If no specific guidelines are provided, CDC recommends discarding the vial within 28 days (CDC 2011)**
3. Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. (Note: Medication containers include syringes, medicine cups, and basins.) (The Joint Commission 2010)
4. **Syringes taken from a multi-dose vials must be labeled with date, time, and staff initials. If not used within 24 hours, it must be discarded no later than 24 hours.**
5. All clients receiving medications also **must** receive written or verbal instructions including the name, purpose and appropriate administration technique for each drug.
6. Patient package inserts **must** be available for IUCs, hormonal contraceptives, and other estrogenic and progestational substances.
7. Patient drug information should be provided on all other drugs dispensed.
8. The nature of the client education provided should be documented in the medical record.

Planned Parenthood of the St. Louis Region and Southwest Missouri

Staff Inservice/Training/Meeting

Date 2/27/13 Topic Medical Staff Training

Presenter/Trainer Susan Bender, NP & Celeste Smith, LCSW

Time 9:45am -10:45 Site RHS (Attach agenda and handouts)

Print Name	Signature & Title	Site
1 Carla Garner		RHS
2 Elaine Dostal		RHS
3 Stacey Honea		RHS
4 Elaine Lemus	Elaine Lemus	RHS
5 Kimberly Jones	Kimberly Jones RN	RHS
6 Alicia King		RHS
7 CALVIETTE (TISA) DUKES	Calvette Dukes	RHS.
8 S Bender	S Bender WHNP BC	RHS
9 Celeste Smith		RHS
10		
11		
12		
13		
14		
15		

CONFIDENTIAL: FOR QARM PURPOSES ONLY L1170 and L1171

Planned Parenthood of the St. Louis Region and Southwest MO

Clinical Quality Assurance Meeting

Original Date: 1/30/13; Rescheduled Date: 2/6/13

Agenda

1) Review of Patient Care
    a. Intraoperative and Postoperative Complications and Occurrences — Sevic, Eisenberg
        i. Last Quarterly Report 2012
        ii. Annual Report 2012 (internal) and AIMS Report — Spencer
    b. Care by procedure / gestational age
        i. Medication
        ii. Surgical
            1. 17 weeks and under
            2. 18 weeks and over
    c. Identification of any problems
    d. Action plans

2) Transfers to Hospital — Eisenberg, Gianino, Kogut
    a. Administrative, Physician, Committee Review
    b. Security and HIPAA systems
    c. Identification of any problems
    d. Action plans

3) DOHSS Inspection — Management Team
    a. Results and findings
    b. Action Plan
    c. Ensuring full compliance with state/local laws and regulations

4) Accreditation — Spencer, Gianino
    a. Plans and Time lines to achieve full accreditation
    b. Agency Involvement

5) Audits — Bender, Moran, Spencer

6) Research Report — Eisenberg, Kogut

7) Old Business — All
    a. Follow up to any previously identified issues
        i. Continuing pregnancies
        ii. Consents
        iii. Next gen audits
        iv. Infection Control Committee

New Business and Announcements — All

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Planned Parenthood of the St. Louis Region and Southwest MO

Clinical Quality Assurance Meeting

Original Date: 1/30/13; Rescheduled Date: 2/6/13

Present: Eisenberg, D, Med Dir; Weisbart, E, Board; Gianino, P, CEO; Bender, S, Clinical Manager; Spencer, C, Training and Quality Systems; Moran, J, Dir HCs; Smith, C, Dir SS; Sevic, N, Data and Quality Compliance; Kogut, M, VP Pt Services

1) Review of Patient Care
    a. Intraoperative and Postoperative Complications and Occurrences — Sevic, Eisenberg
        i. Last Quarterly Report 2012
        ii. Annual Report 2012 (internal) and AIMS Report — Spencer
    b. Care by procedure / gestational age
        i. Medication
        ii. Surgical
            1. 17 weeks and under
            2. 18 weeks and over
    c. Identification of any problems
    d. Action plans

- Reports are attached
- All within expected standards of care
- Complication rates are low and within standard of care
- Patients both under and over 18 weeks of care have been managed well
- No specific identification of problems
- Action Plans: Medical Director requests comparison of current year to previous years for our trend in complications – Sevic to provide

2) Transfers to Hospital — Eisenberg, Gianino, Kogut
    a. Administrative, Physician, Committee Review
    b. Security and HIPAA systems
    c. Identification of any problems
    d. Action Plans

- In a three month period of time same number as in full 2011 year
- Upon analysis, appropriate transfers, patient care and decision-making was handled well, good patient care, no consistent theme or medical condition
- Reasonable decision making and time in center before transfer occurred
- Newest provider had 3 of the transfers – for new trainees this is expected, i.e. that transfers may be higher
- Analysis on three fronts:
    - CEO, VP of Pt Services, and Medical Director identified and discussed after the first 3 transfers. While not desired outcome, all fell within potentially expected outcomes

- Physicians – 3 primary attendings – and the administrative management team discussed 1/31/13 and came to same conclusion; recommendations for some limits on who we serve made and under discussion. Medical Director drawing up guidelines based on discussion
- CQ Committee 2/6/13 also looked at data

- Positive – we have greater continuity of care for patients due to our relationship with Wash U and the procedure of notifying the family planning fellow
- Action: Will update our ambulance transfer form to include: when called, when arrived, when pt discharged to EMS (and effective 2/18/13), when ambulance leaves the premises
- Action: CEO to contact BJC ED regarding potential for picketers and how handled
- Action: CEO to contact EMS for guidelines on the minimal information that must be shared with 911 calls to ensure safety and protect confidentiality
- Action: Staff to be retrained on making the calls after we get this information – Management team – ensure we identify if the call is urgent or emergent
- Action: CEO to work with operations regarding a way to limit the picketers from having full visual access to client as she is being transported – increase patient privacy

3) DOHSS Inspection — Management Team

a. Results and findings
b. Action Plan
c. Ensuring full compliance with state/local laws and regulations

- Surprise audit on 1/30 and 1/31 with 4 auditors
- Part of our licensing and partly due to concerted complaints
- Awaiting formal findings from state within 10 days of audit
- Will have 10 days to return our POA
- Summary of findings to committee:
  - Quality medical care with no indication of any violations of regulations
  - Some improvements on medication inventory; dust in select areas; updating some equipment; and increasing our infection control activities
- Committee was given the components that must make up the QA work
  - This agenda was changed to accommodate those issues
- Action Plan: management team to meet and agree upon immediate and long range procedures, training, changes to ensure improvements
- Action Plan: to respond to any cited deficiencies within 10 days of report

4) Accreditation — Spencer, Gianino

c. Plans and Time lines to achieve full accreditation
d. Agency Involvement

- Accreditation is Oct 9 – 11, 2013
- Plan is to send all documents by July 17, 2013
- Currently, all departments working on their EOPs
- Action: Patient Services, complete all manuals by April 30, 2013

Americans United for Life

5) Audits — Bender, Moran, Spencer

a. Vasectomy

i. Overall very good
ii. First full year at RHS – saw 63 men – a large increase over previous years
iii. One system issue – not enough follow up with patients to remind them of post op semen check
iv. Had turnover in the staff member who was handing this task – new person has been trained

b. Colpo and Pap Audits
   i. With new pap standards, many less colpos
   ii. Overall very good – a few issues that were resolved quickly
   iii. The colpo correlation log is / will be on line and reviewed by MDs
      1. Sign off 2 x per year
   iv. Lead NP able to audit via electronic record

c. Center audits
   i. With Next Gen, trying to audit different medical / clinical issues to ensure documentation
   ii. Action: Need to establish standards for what % of compliance is necessary per criteria
      1. Ex: consents would want to see 100%
      2. Patient Education forms could be lower
   iii. Action: Need to ensure NPs and support staff are clear on who doing what and limit redundancy
      1. Ongoing discussion – Dir of HCs and Clinical Manager with Training and Quality Systems will continue this
   iv. Recommendation: put them in "buckets" by priority / risk
      1. Must have for medical; or must have for financial
      2. Good to have

d. Infection control audits for HCs and RHS
   i. Quarterly audit listing both compliance and non- compliance areas
   ii. Overall good with some improvements noted
   iii. New Committee will address any new audit tools and how to improve outcomes

6) Research Report — Eisenberg, Kogut

a. Roche project is ending – enrollment has been completed; in final stages of the reviews/audits to ensure all paperwork
b. Snafu with consents that has been remedied.
   i. All were signed
   ii. Not all clients took one with them – our SOPs state they will be given one
   iii. Had to send all of those a certified copy
c. RLP
   i. Has begun at SG and CWE
   ii. Not yet enrolling enough patients – will be changing our use of staff to meet numbers
d. New industry sponsored one in discussion and analysis right now on the use of progestin contraceptives as quick start when mife is given
   i. Not yet approved and no budget yet

7) Old Business — All

a. Follow up to any previously identified issues
   i. Continuing pregnancies – No need to continue discussion - resolved
   ii. Consents – continue to track this and check for improvements
   iii. Next gen audits – continue to track this and decide on thresholds

iv. Infection Control Committee – continue to monitor the establishment of and the work of this group

8) New Business
   a. Worker's Comp Claims – up
      i. Few more splashes and sticks
      ii. Do not think it is a system problem – staff were counseled and systems analyzed
      iii. Some increase to our rates; Looking for new carrier as ours is getting out of the WC business

Submitted: Mary M Kogut, VP of Patient Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 1, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***PoC Approval***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Licensure & Complaint Survey conducted on ***January 31, 2013*** has been received in our office and forwarded to the surveyor(s). We want you to know the surveyor(s) has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 21, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Revisit Survey***

Dear Mary Kogut:

Please see attached results of the recent follow-up survey of ***March 19, 2013***. This relates to the Licensure & Complaint survey conducted ***January 31, 2013***. Your facility is now in compliance with Licensure requirements for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 03/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An onsite unnanounced revisit survey was conducted on 03/19/13. The facility was found to be in substantial compliance with the rules and regulations for Abortion Facilities found at 19 CSR 30-30.060.	{L 000}		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

October 21, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00088230***

Dear Mary Kogut:

The results of the recent offsite complaint survey regarding your facility on ***September 19, 2013*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	09/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An off-site complaint investigation was conducted from 09/18/13 to 09/19/13. (Complaint MO00088230). The complaint was unsubstantiated. The facility was found to be in substantial compliance with CSR 30-20.060.	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 01/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An off-site complaint investigation was conducted from 10/22/13 - 01/06/14. (Complaint MO00089143). The complaint was unsubstantiated. The facility was found to be in substantial compliance with CSR 30-20.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

January 30, 2014

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

The results of the recent survey conducted at your facility on ***January 21, 2014*** indicate that your facility is in compliance with the Medicare regulations and State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	01/21/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An unannounced on-site state licensure survey was conducted at this facility on 01/21/14, in conjunction with an allegation survey for complaint #MO00089716. The complaint was unsubstantiated, and the facility was found to be in substantial compliance with CSR 30-20.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

August 5, 2014

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint MO00095990***

Dear Mary Kogut:

The results of the recent off site survey conducted on ***July 28, 2014*** indicate that your facility is in compliance with the State Licensure regulations CSR 30-20.060.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 07/28/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Organization and Management for Abortion Facilities at CSR 30-20.060. The complaint is unsubstantiated with no deficiencies. #MO00095990- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.060	L 000		

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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 22, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Offsite Self Report Review***

Dear Mary Kogut:

An offsite investigation was conducted from ***01/11/16*** to ***01/12/16***. Please see attached results. Your facility was found to be in compliance with the ***Licensure*** requirements for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 01/12/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted from 01/11/16 to 01/12/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00110832 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 02/10/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 02/10/16 to 03/11/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00111719 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30-060.	L 000		

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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 30, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00113026***

Dear Mary Kogut:

The results of the recent offsite complaint survey conducted on ***March 23, 2016*** through ***March 28, 2016*** indicate that your facility is in compliance with the State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 03/23/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted from 03/23/16 to 03/28/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00113026 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060	L 000		

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 27, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00114829***

Dear Mary Kogut:

The results of the recent unannounced allegation survey conducted at your facility on ***May 17, 2016*** and continued off-site until ***May 25, 2016*** indicate that your facility is in compliance with the State Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/25/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced allegation survey was conducted on 05/17/16, and continued off-site until 05/25/16, for complaint #MO00114829. The allegation was found to be unsubstantiated.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

July 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Compaint # MO00116700***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff regarding your facility on ***July 12, 2016*** indicate that your facility is in compliance with the Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 07/12/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted on 07/12/16 for the purpose of review of one complaint, #MO00116700, in relation to the Missouri Regulations for Abortion Facilities. The complaint was unsubstantiated and the facility was found to be in substantial compliance with 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

September 9, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00118398***

Dear Mary Kogut:

The results of the recent survey conducted at your facility from ***August 25, 2016*** through ***September 7, 2016*** indicate that your facility is in compliance with the State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 09/07/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 08/25/16 through 09/07/16 for review of a complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00118398 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

October 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00119763***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***September 30, 2016*** and concluded on ***October 4, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 10/04/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 09/30/16 to 10/04/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00119763 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 9, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint MO00120615***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***November 7, 2016*** and concluded on ***November 8, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 11/08/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 11/07/16 to 11/08/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00120615 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 16, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00121121***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***November 14, 2016*** and concluded on ***November 15, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 11/15/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 11/14/16 to 11/15/16 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00121121 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

December 20, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey # MO00121661***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***December 7, 2016*** and concluded on ***December 19, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 12/19/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 12/07/16 to 12/19/16 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00121661 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 12, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint #MO00125526 Survey***

Dear Mary Kogut:

The results of the recent survey conducted on ***May 1, 2017*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/01/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 03/20/17 sporadically through 05/01/17 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00125526 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 12, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00126207 Survey***

Dear Mary Kogut:

The results of the recent survey conducted on ***May 1, 2017*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/01/2017

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L 000	Initial Comments An investigation was conducted from 04/04/17 sporadically through 05/01/17 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00126207 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services

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L 000	Initial Comments An onsite, unannounced state licensure survey to determine compliance with 19 CSR 30-30.050 through 19 CSR 30-30.060 for Abortion Facilities was conducted from 05/23/17 to 05/25/17. See below for findings:	L 000		
L1106	19 CSR 30-30.060(1)(A)(3) Bylaws of the governing body shall Bylaws of the governing body shall require that an individual who complies with paragraph (1)(A)2. of this rule shall be in charge in the absence of the administrator. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to include in their bylaws the person or position in charge of the facility in the absence of the administrator. The facility performs an average of 270 procedures per month. On the first day of the survey, there were 17 cases. Findings included: 1. Review of the Facility Bylaws, Article 10, Operation of Health Care Facility, dated 03/28/17 showed: - The Vice President of Patient Services and Education (VP) and her delegate shall be responsible for overseeing the day-to-day operations of the facility; and - The VP must meet one of the following qualifications: (i) a physician licensed to practice medicine within the State of Missouri; (ii) a registered nurse licensed to practice nursing within the State of Missouri; or (iii) an individual who has at least one year of administrative experience in the health care industry.	L1106		

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L1106	Continued From page 1 Note: The bylaws failed to specifically designate who would be in charge in the absence of the administrator and what qualifications that delegate must meet. 2. During an interview on 05/23/17 at 2:05 PM, Staff A, Vice President of Patient Services and Education, stated that: - Her position was equivalent to the administrators position in the regulations; - She was responsible for day-to-day operations; - She did not have a policy that indicated who would be in charge in her absence; and - She agreed the bylaws did not specify who would be in charge in her absence or the qualifications of that individual.	L1106		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to: - Ensure staff followed current acceptable	L1128		

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L1128	Continued From page 2	L1128		

standards of practice for hand hygiene;
- Transport soiled instruments in a covered, leak-proof container labeled with a bio-hazard label to indicate potentially infectious objects;
- Follow manufacturers recommendations for use of germicidal wipes; and
- Ensure a sanitary environment was preserved by providing intact (free of holes) and easily cleanable surfaces (free of rust) that will not harbor bacteria and transmit infections.

The facility performs an average of 270 procedures per month. On the first day of the survey, there were 17 cases.

Findings included:

Hand Hygiene findings

1. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed:
- Indications for hand hygiene:
 * Contact with a patient's intact skin;
 * Contact with environmental surfaces in the immediate vicinity of patients; and
 * After glove removal.
- Indications for, and limitations of, glove use:
 * Hand contamination may occur as a result of small, undetected holes in the examination gloves;
 * Contamination may occur during glove removal;
 * Wearing gloves does not replace the need for hand hygiene; and
 * Failure to remove gloves after caring for a patient may lead to transmission of microorganisms from one patient to another.

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L1128	Continued From page 3 2. Review of the Association for Professionals in Infection Control (APIC), scientific guidelines referred to the CDC Morbidity and Mortality Weekly Report titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed the following: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 3. Review of the facility's "Infection Control Manual", dated 2017, showed resources that could be used to answer infection prevention questions and review for updated information and trends included: - Association for the Advancement of Medical Instrumentation (AAMI); - APIC; -Association of Perioperative Registered Nurses (AORN); - CDC; and - Occupational Safety and Health Administration (OSHA). 4. Review of the facility's "Infection Control Manual," policy titled, "Standard Precautions, Hand Hygiene, PPE," dated 2017, showed: -Good hand hygiene, including the use of alcohol-based hand rubs and hand washing with soap and water is critical to reduce the risk of	L1128		

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L1128	Continued From page 4 spreading infections in healthcare settings is recommended by the CDC and the World Health Organization because of its activity against a broad spectrum of pathogens. - Hand hygiene is the most important single procedure for preventing health-care associated infections. - Key situations where hand hygiene should be performed include: * Before touching a patient, even if gloves are worn; * Before exiting the patient's care/procedure area after touching the patient or patient's immediate environment; * After contact with blood, body fluids, excretions, or dressings; * Prior to performing an aseptic task; * If hands will be moving from a contaminated-body site to a clean-body site during patient care; and * After glove removed. 5. Observation on 05/23/17 from 10:20 AM to 10:40 AM, in the procedure room showed: - At 10:27 AM Staff JJ, Physician, and Staff LL, Physician, both donned gloves but failed to perform hand hygiene. Staff JJ performed a vaginal exam on the patient, removed her right glove, failed to perform hand hygiene, then reached into her back pocket and retrieved a glove and donned it. - Staff JJ sprayed a soap mixture in the patient's vaginal area and injected Lidocaine (numbing medication), then removed her soiled gloves, failed to perform hand hygiene, and donned sterile gloves. - At 10:37 AM, after the procedure was completed, Staff LL removed her gloves but failed to perform hand hygiene before exiting the room.	L1128		

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L1128	Continued From page 5 6. Observation on 05/23/17 from 11:00 AM to 10:15 AM, in the procedure room showed: - Staff JJ and Staff LL entered the room, performed hand hygiene and donned gloves; - At 11:02 AM, Staff LL rubbed her nose while wearing her gloves, she then failed to remove her soiled glove and perform hand hygiene. Staff JJ documented in the patient's medical record while wearing gloves, she then removed her gloves but failed to perform hand hygiene. - At 11:06 AM, Staff JJ and Staff LL donned clean gloves but failed to perform hand hygiene first. Staff JJ performed a vaginal exam, removed her soiled glove from her right hand, failed to perform hand hygiene, then reached into her back pocket and retrieved a glove and donned it. - Staff JJ sprayed a soap mixture in the patient's vaginal area and injected Lidocaine, then removed her soiled gloves, failed to perform hand hygiene, and donned sterile gloves. 7. Observation on 05/24/17 from 9:30 AM to 10:08 AM, in the procedure room showed: - At 9:34 AM Staff JJ donned gloves but failed to perform hand hygiene and Staff GG, Physician, wore gloves and attempted to restart Patient #25's intravenous (IV - small catheter inserted into a vein for administering medication and fluid) line; - At 9:38 AM Staff GG disposed of a bloody syringe and placed a dressing on the patient's arm, removed her soiled gloves and donned clean gloves. She failed to perform hand hygiene after removing her soiled gloves. She then leaned against a wall with her gloved hands behind her back, went to the electronic medical record and documented, picked up the paper medical record and reviewed it, then removed her gloves. She failed to perform hand hygiene after she removed her gloves.	L1128		

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L1128	Continued From page 6 - At 9:47 AM Staff GG stood with her gloved hands on her hips. Staff JJ removed her gloves but failed to perform hand hygiene. - At 9:47 AM Staff GG removed her gloves, handled her cell phone, and exited the room. She failed to perform hand hygiene after removing her gloves. - At 9:49 AM Staff JJ rubbed her nose and pushed her glasses up while wearing gloves. She failed to remove her gloves and perform hand hygiene. - At 9:57 AM Staff GG and Staff JJ entered the procedure room and donned gloves. They failed to perform hand hygiene before donning the gloves. - At 9:58 AM Staff JJ removed laminaria (kelp species) sticks (a thin rod of dried laminaria used to slowly dilate the cervix) from the patient's cervix. Staff GG administered additional IV medication while wearing gloves, picked up a piece of trash from the floor, stood with her gloved hands on her hips, then documented in the electronic medical record. She failed to change her gloves and perform hand hygiene. - At 10:00 AM Staff GG removed her gloves and partially stepped out of the procedure room then returned. She failed to perform hand hygiene after she removed her gloves and when she re-entered the room. She documented in the patient's electronic medical record. - At 10:01 Staff JJ removed her soiled gloves after removing the laminaria sticks and donned clean gloves. She failed to perform hand hygiene between glove changes. - At 10:02 Staff GG donned gloves. She failed to perform hand hygiene. - At 10:03 Staff JJ administered Lidocaine medication, removed her gloves, and donned sterile gloves. She failed to perform hand hygiene between glove changes.	L1128		

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L1128	Continued From page 7 8. During an interview on 05/25/17 at 11:50 AM, Staff CC, Medical Director, Physician,: - Questioned if hand hygiene between glove changes was a new standard; - Wanted to know whose standard it was; - Stated that the procedures they performed were not "sterile"; and - Questioned if it was facility policy to perform hand hygiene after glove removal. Instrument transport findings 9. Review of the AORN, "Guideline for Cleaning and Care of Surgical Instruments," dated 2016, showed: - Recommendation IV.b. * Soiled instruments must be transported to the decontamination area in a closed container or enclosed transport cart. The container or cart must be: Leak proof; Puncture resistant; Large enough to contain all contents; and Labeled with a fluorescent orange or orange-red label containing a bio-hazard legend. * Labeling the transport containment device communicates to others that the contents are potentially infectious. - Recommendation IV.b.1. * Bio-hazard labels should be affixed so as to prevent separation from the contents. When appropriate to the configuration of the contents, a red bag or red container may be used instead of a label to indicate contaminated waste. 10. Review of the (AAMI document titled, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities, ST79," dated 2010, showed:	L1128		

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L1128	Continued From page 8 - N.2.2.5 Transport of instruments to the decontamination area: * During transport of instruments from the point of use to the decontamination area, appropriate precautions (e.g., use of a closed transport container) should be taken to avoid personnel exposure to blood-borne pathogens, contamination of the work environment, and further contamination of the instruments. 11. Review of the facility's "Infection Prevention Manual", policy titled, "Handling of Contaminated Furniture/Equipment/Linen/Instruments/Supplies," dated 2017, showed contaminated instruments should be transported covered. 12.Observation on 05/23/17 at approximately 10:37 AM after Patient #20's procedure showed Staff M, HCA, partially wrapped the soiled instruments in the disposable sterilization wrap and a disposable pad, then removed the soiled instruments from the procedure room. She failed to transport the instruments to the decontamination room in a closed, leak-proof container with a biohazard label affixed to the container. 13. Observation on 05/23/17 at 11:16 AM after Patient #19's procedure showed Staff M partially wrapped the soiled instruments in the disposable sterilization wrap and a disposable pad then removed the soiled instruments from the procedure room. She failed to transport the instruments to the decontamination room in a closed, leak-proof container with a biohazard label affixed to the container. 14. During an interview on 05/24/17 at 10:25 AM, Staff G, Health Center Manager, stated that they did not use closed leak-proof containers with a	L1128		

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L1128	Continued From page 9 biohazard label but thought it would be a good idea. Germicidal Wipes findings 15. Review of the manufacturers instructions for use for the McKesson (brand) Disposable Germicidal Surface Wipes showed: - Cleaning and Disinfection Instructions * Use a fresh wipe to pre-clean surfaces of all gross filth and heavy soil. * Repeat as necessary until all surfaces are visibly clean. * To effectively disinfect the pre-cleaned surfaces, use a fresh wipe or turn the wipe over to the clean side to thoroughly wet the surfaces and allow surface to remain wet for the appropriate time indicated for the purpose intended. * Effectively kills the multiple microorganisms at room temperature with a two minute contact time when used as directed. * Used in surgical centers and rooms and areas/facilities concerned with the hazards of cross contamination from infectious microorganisms. 16. Review of the facility's "Infection Prevention Manual", policy titled, "Cleaning, Disinfection, and Sterilization," dated 2017, showed: -Procedure Room Practices: Disposable paper coverings may eliminate the need to disinfect between clients. Disinfection must be done if paper covering becomes torn, wet, or visibly soiled. - If paper covering is used, change the paper covering and disinfect the surface as needed (i.e., when the paper covering becomes saturated with blood or body fluids.) -Spray on disinfectant. Leave on surface for	L1128		

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L1128	Continued From page 10 number of minutes as per product directions ("contact time"). 17. Observation on 05/23/17 at 10:40 AM, after Patient #20's procedure showed Staff J, Environmental Services, wiped the bed with McKesson germicidal wipes. She failed to allow for two minutes of contact time. During an interview immediately after the observation, Staff K, Flow Facilitator, stated that the germicidal wipes dried in 30 seconds and agreed that Staff J did not allow two minutes of contact time. 18. Observation on 05/23/17 at 10:45 AM in the recovery area showed Staff N, Registered Nurse, cleaned a chair with a germicidal wipe but failed to allow two minutes of contact time. 19. Observation on 05/23/17 at 11:20 AM, after Patient #19's procedure showed the paper liner covering the bed was partially saturated with blood in several spots, and there was additional blood on the procedure table that had leaked through the paper liner. Staff L, MA, removed the paper liner and wiped the bed with a germicidal wipe. She failed to allow two minutes of contact time. During an interview immediately after the observation, Staff L stated that the contact time was 15 seconds. Oxygen Tanks findings 21. Review of the AORN, "Guideline for Environmental Cleaning," dated 2016, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative RN should assess the perioperative environment frequently for	L1128		

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L1128	Continued From page 11 cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. 22. Observation on 05/23/17 from 9:30 to 9:40 AM of procedure rooms #1, #2, and #3 showed each had an oxygen tank in the room. The tanks were soiled and had adhesive residue with dirt stuck on the tanks. 23. During an interview on 05/24/17 at 10:25 AM, Staff G agreed the oxygen tanks were not clean and stated that staff did wipe the tanks down when they got new tanks but the residue did not come off with routine wiping.	L1128		
L1136	19 CSR 30-30.060(1)(B)(12) The administrator shall be responsible The administrator shall be responsible for ensuring that the provisions of Chapter 188, Regulation of Abortions, RSMo 1986 are adhered to. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to submit complication reports to the Missouri Department of Health and Senior Services (Department) as required by statute. The facility performs an average of 270 procedures per month. On the first day of the survey, there were 17 cases. Findings included:	L1136		

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L1136	Continued From page 12 1. Review of Missouri law 188.052(2);(3) RSMo, showed: - An individual complication report for any post-abortion care performed upon a woman shall be completed by the physician providing such post-abortion care. This report shall include: (1) The date of the abortion; (2) The name and address of the abortion facility or hospital where the abortion was performed; (3) The nature of the abortion complication diagnosed or treated. 3. All complication reports shall be signed by the physician providing the post-abortion care and submitted to the department of health and senior services within forty-five days from the date of the post-abortion care. 2. Review of 19 CSR 30-30.050(1)(D) showed "complication" to be defined in the regulation as: "Complication-includes, but is not limited to, hemorrhage, infection, uterine perforation, cervical lacerations and retained products." 3. Review of the facility's "Complication and incident log"-an internal database report dated 05/24/17 and used by facility staff to follow up on patients who sought post-abortion care, showed multiple patients being treated at the facility for issues that met the regulatory definition of complication. Follow up care was documented in the complication log, but there was no evidence of any associated complication reports being submitted to the Department. 4. Review of the facility's "QA Manual" dated 2017, showed policies regarding various reports sent to the state: - "CVR reports are state reports that are submitted [to the Department] by the 10th of the month before for all abortion procedures	L1136		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	05/25/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNED PAF	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1136	Continued From page 13	L1136		

performed." This report corresponds to the mandatory "Induced Termination of Pregnancy" reports required to be submitted to the Department.
- "Board of Healing Arts report is a state report that is required by the State for all Abortion procedures for over 20 weeks [gestational age]." The report corresponds to the mandatory viability determination report.
- However, there was no facility policy specific to the submission of post-abortion complication reports to the Department.

5. During an interview on 05/24/17 at 3:05 PM, Staff D, Director of Quality, stated:
- The facility and the physicians were not sending any complication reports at this time.
- The facility had become fully aware of the complication report requirement in the last few months, and had discussed the issue internally, but wanted a clearer definition of complication before they would comply.

6. During an interview on 05/25/17 at 10:23 AM, Staff B, President and CEO stated:
- The facility had become aware of the complication reporting requirement after communications with the Department "several months ago."
- The facility had not sent in any complication reports even once they became fully aware of the requirement.
- The facility had requested a formal meeting with the Department and other stakeholders several times to seek clarification on the requirement, but so far no such meeting was planned, and the facility was waiting for this meeting before they believed they could adequately comply with the requirement.

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	05/25/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNED PAR	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An onsite, unannounced state licensure survey to determine compliance with 19 CSR 30-30.050 through 19 CSR 30-30.060 for Abortion Facilities was conducted from 05/23/17 to 05/25/17. See below for findings:	L 000		
L1106	19 CSR 30-30.060(1)(A)(3) Bylaws of the governing body shall Bylaws of the governing body shall require that an individual who complies with paragraph (1)(A)2. of this rule shall be in charge in the absence of the administrator. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to include in their bylaws the person or position in charge of the facility in the absence of the administrator. The facility performs an average of 270 procedures per month. On the first day of the survey, there were 17 cases. Findings included: 1. Review of the Facility Bylaws, Article 10, Operation of Health Care Facility, dated 03/28/17 showed: - The Vice President of Patient Services and Education (VP) and her delegate shall be responsible for overseeing the day-to-day operations of the facility; and - The VP must meet one of the following qualifications: (i) a physician licensed to practice medicine within the State of Missouri; (ii) a registered nurse licensed to practice nursing within the State of Missouri; or (iii) an individual who has at least one year of administrative experience in the health care industry.	L1106		

Janice Thomas VP of Patient Services 5/30/17

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1106	By-Law of the Governing Body Finding - Section 2 of the By-Laws of Reproductive Health Services of Planned Parenthood of the St. Louis Region (RHS) have been revised to reflect the title of the person in charge of RHS operations in the absences of the administrator and what qualifications that delegate must meet and were approved May 30, 2017.	May 30, 2017	CEO & President		F1 Revised RHS- By-Laws
L1128	Instrument Transport Finding - RHS has implemented the transport of soiled instruments in a covered, leak-proof container labeled with bio-hazard labels on all sides to indicate potentially infectious objects. The circumstances for use was reviewed with all RHS Medical Assistants and nurses by the manager on May 25, 2017 The Infection Prevention Manual, Section 2 Cleaning, Disinfection and Sterilization was revised to reflect the use of the lidded leak proof covered labeled rigid containers..	May 25, 2017	Health Center Manager III	The manager will conduct a review of all Medical Assistants engaged in the transport of instruments from the procedure rooms on a rolling basis over the next 30 days to ensure 100% use of the lidded leak proof containers and document the results.	F1 Pictures of container, Infection Prevention Manual, page 16
L1128	Germicidal Wipes Finding - The use of the McKesson Disposable Germicidal Surface Wipes was reviewed with all Medical Assistants, lab personnel, nursing staff and sonographers highlighting the 2 minute exposure time for surface contact with the germicidal solution. The manufacturers insert for this product was used for this review. During daily terminal cleaning staff will ensure that all environmental surfaces, chairs, counters, etc., are free of any breaches (holes, cracks) and free of rust. Additionally, all staff are to note any breaches or	May 25, 2017	Health Center Manager III	The manager will observe and document all Medical Assistants, lab personnel, nursing staff and sonographers cleaning surfaces with the McKesson Disposable Germicidal Surface Wipes to ensure adherence to the 2 minute surface contact time, that examine tables are appropriately cleaned in the event of a soiled or torn paper liner by July 1, 2017.	F1 Infection Prevention Manual, page 19

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	presence of rust observed during the course of their daily activities and report them to facilities manager for repair/remediation. Special care will be taken in cleaning of those surfaces until a repair/remediation. The Infection Prevention Manual was also revised to reflect the proper usage of the disinfecting wipes in Section 2 Cleaning, Disinfection and Sterilization.				
L1128	Hand Hygiene Finding - A retraining of all physicians, fellows and residents on proper hand hygiene with emphasis on proper technique on hygiene between glove changes. This has begun for all providers who have completed a shift as May 30, 2017. This will be completed for remaining providers on their next shift prior to service provision to patients. The Affiliate Risk Management Infection Prevention Manual, Hand Hygiene (Page 60) was used for this retraining. This information will also be reviewed during the June 2017 all provider meeting. The training is conducted by the Medical Director and Health Center Manager.	June 30, 2017	Medical Director	The Health Center Manager/designee will observe and document the results of the observations of each physician, fellow, and resident during their shift over the next 30 days. The standard will be the ARMS Infections Prevention Manual, Hand Hygiene (Page 60) with a standard of 100% compliance.	F1 ARMS Infection Prevention Manual, Page 60
L1128	Oxygen Tank Findings – In the interim clear plastic sleeves will be placed over each oxygen tank until a vendor is found that can provide clear covers for the current oxygen tank.	May 30, 2017	Health Center Manager III	The Health Center Manager and Flow Facilitator will ensure the oxygen tanks remain covered in the clear sleeve or cover during daily monitoring	
L1136	Complication Report Finding - RHS will submit complication reports on a going-forward basis. RHS understands that DHSS will consider the filing of reports on a going-forward basis to be sufficient to correct this deficiency.	May 31, 2017	VP of Patient Services & Education	The VP of Patient Services with the Director of Quality will initially conduct a review of all forms and spot check forms to to ensure completed appropriately. .	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	As indicated during the inspection, RHS was not clear on exactly what needs to be reported on a complication report. RHS now understands that DHSS will consider reporting of the complications listed in regulation 19 CSR 30-30.050(1)(D) (hemorrhage, infection, uterine perforation, cervical lacerations and retained products) and on a complication report form prepared by the Department to be sufficient to meet the complication reporting requirement and to correct this deficiency. RHS further understands that DHSS will be issuing a modified complication reporting form that will remove two categories (cramps and skin reaction) from the form. RHS will utilize the current form until a new form is issued. RHS will begin using the new form as soon as it is available.				

Section 1: Ambulatory Surgical Center. The Corporation may operate a licensed abortion facility or ambulatory surgical center within the State of Missouri at which abortion and/or other pregnancy termination services and procedures, related counseling services and other related services are provided ("Facility").

The Board shall have full legal responsibility for determining, implementing and monitoring policies and procedures governing the Facility's total operation and for ensuring that those polices are administered in a manner so that the Facility provides appropriate care in a safe environment.

Section 2: Facility Manager and Administrator. The President/CEO shall select and the Corporation shall employ a Surgical Services Manager for the Facility ("Manager") who is the day to day operations manager. She is also the delegate and acting supervisor for the VP when the VP is absent. A secondary delegate is the Clinical Manager, an advanced practice NP. The administrator is the Vice President of Patient Services and Education. The VP shall report to the President/CEO. Subject to direction, guidance and authority granted by the President/CEO, the VP and her delegate shall be responsible for overseeing the day-to-day operations of the Facility. The VP and her delegate must meet one of the following qualifications: (i) a physician licensed to practice medicine within the State of Missouri; (ii) a registered nurse licensed to practice nursing within the State of Missouri; or (iii) an individual who has a least one year of administrative experience in the health care industry.

In the Administrator's (i.e Director) absence, only an individual who meets one of the qualifications described in the immediately preceding paragraph may be left in charge of the Facility.

The Officers of the Corporation shall promptly provide written notification to the Missouri Department of Public Health and Senior Services of any change in the person employed by the Corporation as the Facility's Director.

The President/CEO shall select and the Corporation shall employ a Medical Director for the Corporation. The Medical Director shall report to the President/CEO. Subject to direction, guidance and authority granted by the President/CEO, the Medical Director be responsible for overseeing the provision of all medical services provided by the Corporation. This includes, but is not limited to, review and approval of all medical policies and procedures; review of all quality assurance activities and results, and participation in the plan of action for follow-up; review of physician complications; and responsibilities for the screening, approval and reappointment of all physician staff providing abortion or surgical services. The Medical Director shall be a board certified physician, preferably an OBGyn, licensed to practice medicine in the State of Missouri.

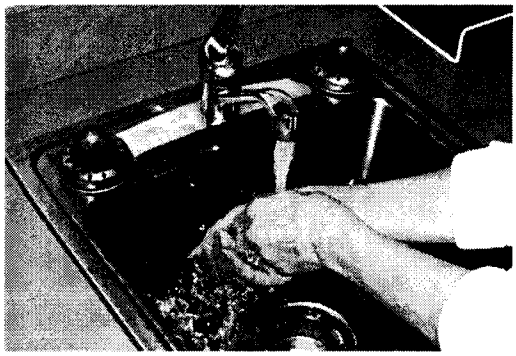
Section 3: Surveyor Access to Facility. Persons duly appointed by the Missouri Department of Health as licensed abortion facilities or ambulatory surgical center surveyors shall be allowed to inspect the Facility at any time the Facility is in operation, consistent with due regard for the medical condition and privacy of the on-site patients.

Section 4: Personnel and Medical Staff Matters. All persons employed or engaged by the Facility, including the Facility's medical staff, nursing, professional and support staff and all counseling staff and volunteers, shall be directly responsible to the VP and his/her supervisory staff, and indirectly responsible to the President/CEO and to the Board.

Hand Hygiene

Good hand hygiene, including use of alcohol-based hand based rubs and hand washing with soap and water is critical to reduce the risk of spreading infections in health care settings. Use of alcohol-based hand rub as the primary mode of hand hygiene in healthcare settings is recommended by the CDC and the World Health Organization because of its activity against a broad spectrum of pathogens.

Hand washing is the #1 protection against transmission of communicable diseases.



Hand hygiene is the most important single procedure for preventing health care-associated infections. Antiseptics control or kill microorganisms contaminating skin and other superficial tissues and are sometimes composed of the same chemicals that are used for disinfection of inanimate objects. Although antiseptics and other hand hygiene agents do not sterilize the skin, they can reduce microbial contamination depending on the type and the amount of contamination, the agent used the presence of residual activity, and the hand hygiene technique followed.

1. Key situations were hand hygiene should be performed include:
    a. Before touching a patient, even if gloves are worn
    b. Before exiting the patient's care/procedure area after touching the patient or the patient's immediate environment
    c. After contact with blood, body fluids or excretions, or dressings
    d. Prior to performing an aseptic task (i.e. placing an IV, preparing an injection)
    e. If hands will be moving from a contaminated-body site to a clean-body site during patient care
    f. After glove removed
2. Use soap and water when hands are visibly soiled (i.e. blood, body fluids). The preferred method of hand decontamination is with an alcohol-based hand rub.

Americans United for Life

Planned Parenthood®
Care. No matter what.

Site: RHS of PPSLR

Staff Training: McKesson Disposable Germicidal Surface Wipes

Staff Attendance	Staff Attendance
Surgical Staff A	Surgical Staff I
Surgical Staff B	Surgical Staff J
Surgical Staff C	Surgical Staff K
Surgical Staff D	Surgical Staff L
Surgical Staff E	Surgical Staff M
Surgical Staff F	Surgical Staff N
Surgical Staff G	Surgical Staff O
Surgical Staff H	

Date: 5/24/17

Subject: Disposable Germicidal Disinfectant Surface Wipes

Trainer: Surgical Staff A, HCM III

Objective: Staff were educated on the contact wait time of two (2) minutes to effectively disinfect surfaces such as chairs, tables, exam tables, lamps, any other counter surfaces, blood pressure machines, etc. in accordance with McKesson Disposable Germicidal Surface Wipes manufacturer instructions.

Attached: McKesson Disposable Germicidal Surface Wipes Directions for Use

L:\2017 State Visit\McKesson_Disposable_Germicidal_Surface_Wipes_Instructions.pdf

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Site: RHS of PPSLR

Staff Training: McKesson Disposable Germicidal Surface Wipes

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Surgical Staff A	Surgical Staff I
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Surgical Staff F	Surgical Staff N
Surgical Staff G	Surgical Staff O
Surgical Staff H	

Date: 5/24/17

Subject: Disposable Germicidal Disinfectant Surface Wipes **Trainer**: Surgical Staff A, HCM III

Objective: Staff were educated on the contact wait time of two (2) minutes to effectively disinfect surfaces such as chairs, tables, exam tables, lamps, any other counter surfaces, blood pressure machines, etc. in accordance with McKesson Disposable Germicidal Surface Wipes manufacturer instructions.

Attached: McKesson Disposable Germicidal Surface Wipes Directions for Use

L:\2017 State Visit\McKesson_Disposable_Germicidal_Surface_Wipes_Instructions.pdf

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

June 2, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Revisit Survey***

Dear Mary Kogut:

Please see attached results of the recent follow-up survey of ***May 31, 2017***. This relates to the Licensure survey conducted ***May 25, 2017***. Your facility is now in compliance with the Licensure requirements for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 05/31/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An onsite Licensure revisit survey was conducted on 05/31/17. The facility was found to be in compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	{L 000}		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

August 17, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00131562***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***August 14, 2017*** and concluded on ***August 15, 2017*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 08/15/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 08/14/17 through 08/15/17 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO 00131562 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

April 6, 2018

Janice Thomas
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: *Licensure Survey*

Dear Janice Thomas:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings (deficiencies) of the survey conducted on ***03/07/2018*** in connection with the Licensure Survey requirements as they pertain to ambulatory surgical centers in Missouri. Please submit a Plan of Correction (POC) stating how you will correct the cited deficiencies. This POC must be submitted within ten (10) calendar days of the date this letter and SOD is received by your facility.

An acceptable plan of correction must contain the following elements:

1. Address each deficiency individually, unless both State and Federal regulations have been cited. For example, A0405 and L1236 often address the same concerns. If the deficiency statement is identical, you may combine the citations and state one Plan of Correction.
2. The plan should state how you will improve the process that led to the deficiency cited. State each component, as indicated. For example, write facility policy, train staff on new process, etc.
3. The plan must include the monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected and /or in compliance with the regulatory requirements. The Plan must include frequency and length of monitoring and tracking procedures to ensure the plan of correction is effective.
4. The plan must include a date when each deficiency will be/has been corrected or completed. In general, we would expect the facility to have a corrective action fully implemented no later than 45 days after the Statement of Deficiencies was received. This date must include when the facility will be in full compliance.
5. Should you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include the expected completion date(s) for each phase. If the phased POC is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.
6. The plan must include the title of the person responsible for implementing and monitoring the plan of correction for each deficiency, and must state how the stated improvement actions will be incorporated into your Quality Assessment and Performance Improvement (QAPI) Program to reduce the likelihood of the deficient practice reoccurring.
7. The first page of the Form 2567 **for each set of regulations cited** must be signed and dated in the block labeled "Facility Representative's Signature."

Even though the deficiency may have been corrected before a Plan of Correction is returned to this office, the plan must be outlined as stated above. The statement "corrected" or "completed" is not an acceptable response. Your POC must specify how these deficiencies were corrected and the date of correction.

Please retain a copy of this letter and the SOD for your reference. We welcome any questions at (573) 751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/07/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/05/18 to 03/07/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on federal regulations, state statute, policy review, record review, and interview, the facility failed to: - Reconcile controlled substances ordered with controlled substances received; - Conduct an annual inventory of controlled substances; and - Ensure a Power of Attorney (POA) was obtained authorizing the person designated to order narcotics for the facility and ensure the POA was readily available for inspection. The Abortion Facility does an average of 315 cases per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of the Drug Enforcement Administration (DEA) Regulation 21 Code of Federal Regulations (CFR) 1301.71(a) showed: - All applicants and registrants shall provide	L1111		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/07/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L1111	Continued From page 1 effective controls and procedures to guard against theft and diversion of controlled substances. 2. Review of the DEA Title 21 CFR, Controlled Substance Act, Part 1305, Subpart B, dated 10/27/70, showed: - §1305.13 Procedure for filing DEA Forms 222. * A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files. * The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser. - §1305.17 Preservation of DEA Forms 222. * The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached. 3. Review of Missouri's 19 CSR 30-1.048(1)(A)-(C), dated 04/30/17, showed: 1) Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed: (A) The name of the substance; (B) Each finished form (for example, ten milligram (10 mg [unit of measure]) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter [ml - unit of measure]) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml vial); and (C) The number of commercial containers of each finished form received from other persons,	L1111		

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L1111	Continued From page 2 including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received. 4. Review of the Control Substance Act of 1970 (Public Law 91-513) requires that complete and accurate records of all receiving and dispensing transactions must be maintained for a period of two years. 5. Review of the facility's copies of completed DEA Forms 222 showed: - The DEA Forms 222 did not have an invoice or packing slip attached to them to reconcile what was ordered with what was received or to track who received the controlled substances; - The DEA Forms 222 did not have an invoice or packing slip attached to them to document the name, address and registration number of the person from whom the containers of controlled substances were received; and - The facility failed to record on Copy 3 of the DEA Form 222 the number of packages received and the dates on which the controlled substances were received. 6. During an interview on 03/07/18 at 3:35PM, Staff A, Vice President Patient Care and Clinical Services, stated that Staff C, Nurse Practitioner (advanced registered nurse), Lead Clinician, and Staff CC, Physician, Medical Director, ordered the narcotics (controlled substances) for the facility. 7. During a telephone interview on 03/07/18 at 3:55 PM, Staff C stated that: - She ordered all Schedule II narcotics but did not receive them when they were delivered to the	L1111		

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facility;
- After she filled out the DEA Form 222 and placed the order, she gave Staff R, Financial Officer, the DEA Form 222 to file in her office;
- When the narcotics were delivered to the facility, Staff S, Maintenance and Receiving, received the narcotics and put them in a double-locked narcotic box located in a cage downstairs;
- Once the narcotics were delivered to the facility, she did not fill in the number of packages received or the date the packages were received on copy 3 of the DEA Form 222;
- She did not reconcile what was ordered with what was received; and
- She was not sure where the packing slips for the controlled substances were.

8. During an interview on 03/07/18 at 4:08 PM, Staff A stated that she was unaware the DEA Form 222 should have been reconciled with the packing slip to show that what was ordered was received.

9. Review of the Missouri State Statue RSMo, Chapter 195, dated 08/28/15, showed:
- 195.050.6: Every person registered to manufacture, distribute or dispense controlled substances under sections 195.005 to 195.425 shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the Department of Health and Senior Services.

10. Review of Missouri's 19 CSR 30 - 1.041(3) (A)-(B), dated 04/30/17, showed:
- Records Requirements. Each registered individual practitioner, institutional practitioner,

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L1111	Continued From page 4 manufacturer, distributor, importer and exporter, shall maintain inventories and records of controlled substances as follows: * (A) Inventories and records of controlled substances listed in Schedules I - II shall be maintained separately from all of the records of the registrant: * (B) Inventories and records of controlled substances listed in Schedules III - V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant. 11. Review of Missouri's 19 CSR 30 - 1.042(3), dated 04/30/17, showed: - Annual Inventory Date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least once a year. The annual inventory may be taken on any date that is within one year of the previous annual inventory date. - Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory was taken. - Controlled substances shall be deemed on hand if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, and substances stored in a warehouse on behalf of the registrant. - For each controlled substance in finished form, the name of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (for example, four 100 tablet bottles or three milliliter (3 ml) vials); the number of commercial containers of each	L1111		

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L1111	Continued From page 5 finished form (for example, four 100 tablet bottles or six three milliliter (3 ml) vials). (Note: Schedule IV drugs included Diazepam (used to treat muscle spasms and anxiety) and Versed (sedative). Schedule II drugs included Fentanyl (narcotic pain medication). 12. Observation on 03/05/18 at 2:20 PM of the narcotic cabinet showed the facility had Diazepam, Fentanyl, and Versed. During an interview upon the observation, Staff J, RN, confirmed that these controlled substances were used by the facility. 13. On 03/06/18 at 2:10 PM staff provided an annual inventory for the facility. The annual inventory provided was not the required separate inventory for Schedule I - II and Schedule III - V controlled substances. The annual inventory list was requested again. (Note: The facility failed to provide the required annual inventory for Schedule I - II and Schedule III - V prior to exit.) 14. Review of the Title 21 Code of Federal Regulations §1305.05 Power of Attorney (POA) showed: * A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. - The power of attorney must be available for inspection together with other order records.	L1111		

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L1111	Continued From page 6 15. During an interview on 03/05/18 at approximately 2:30 PM, Staff J, RN, stated that Staff H, Health Center Manager, ordered medications. 16. During interviews on 03/06/18 at 11:35 AM and 2:10 PM, survey staff requested the POA for the person responsible for ordering controlled substances from Staff A. 17. During an interview on 03/07/18 at 1:30 PM, Staff H stated that she: - Did not order controlled drugs; and - Did not know who ordered the controlled drugs. 18. During an interview on 03/07/18 at 2:00 PM, Staff P, Director of Quality and Infection Control, stated that Staff C was responsible for ordering medications. 19. During an interview on 03/07/18 at 3:20 PM, Staff A stated that Staff R had the POA but they were unable to find it. 20. During an interview on 03/07/18 at 3:35PM, Staff A stated that Staff C and Staff CC ordered the narcotics (controlled substances) for the facility. 21. (Note: The annual inventory and POA were originally requested on 03/06/18 at 11:35 AM. Staff failed to provide the annual inventory and the POA by the time of exit on 03/07/18 at 5:45 PM.)	L1111		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for	L1128		

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L1128	Continued From page 7 identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Ensure staff followed acceptable standards of practice for hand hygiene; - Follow the manufacturer's recommendations for disinfectant dry time; - Follow the manufacturer's recommendations for disinfectant storage; and - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections. The Abortion Facility does an average of 315 cases per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the	L1128		

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immediate vicinity of patients; and
* After glove removal.
- Indications for, and limitations of, glove use:
* Hand contamination may occur as a result of small, undetected holes in the examination gloves;
* Contamination may occur during glove removal;
* Wearing gloves does not replace the need for hand hygiene; and
* Failure to remove gloves after caring for a patient may lead to transmission of microorganisms from one patient to another.

2. Review of the facility's "Infection Prevention Manual" policy titled, "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE)," dated 09/05/17, showed:
- Key situations were [sic] hand hygiene should be performed include:
* Before exiting the patient's care/procedure area after touching the patient or the patient's immediate environment;
* After contact with blood, body fluids or excretions, or dressings; and
* After glove removed.
- Hand-rubs (alcohol-based product) should be used before and after each patient just as gloves should be changed before and after each patient.
- Do not wash or try to re-use disposable (single use, exam) gloves.
(Note: The facility's policy referenced the CDC document noted above.)

3. Observation on 03/06/18 at 9:20 AM showed Staff G, Sonographer (ultrasound technician), completed an ultrasound on Patient #19, wiped off the ultrasound probe with a paper towel, removed one glove, failed to remove both gloves

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L1128	Continued From page 9 and perform hand hygiene, and opened the door with the hand not gloved. 4. Observation on 03/06/18 at 9:44 AM showed Staff I, Sonographer, completed an ultrasound on an unidentified patient, removed the paper that covered the exam table, removed one glove, failed to remove both gloves and perform hand hygiene, rubbed her eye with the hand not gloved, donned the dirty glove, rinsed the vaginal probe with water, wiped it with gauze and placed it in the high-level disinfectant, removed one glove, failed to remove both gloves and perform hand hygiene, rubbed her eye, donned the soiled glove, and cleaned the exam table. 5. During an interview on 03/07/18 at 1:55 PM, Staff H, Health Center Manager, stated that hand hygiene was expected: - Before and after patient care; - Before and after glove use; and - Even if gloves were worn. 6. Review of the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2008, showed: - Disinfect noncritical surfaces with an EPA (Environmental Protection Agency) -registered hospital disinfectant according to the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, many scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, the user must follow all applicable label instructions on EPA-registered products. If the user selects	L1128		

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L1128	Continued From page 10 exposure conditions that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act). 7. Review of the facility's container of McKesson (manufacturer) disinfectant wipes' label instructions for contact time showed to allow the surface to remain wet for two minutes. 8. Review of the facility's "Infection Prevention Manual" policy titled, "Cleaning, Disinfection and Sterilization," dated 09/05/17, showed: - Germicidal wipes (disinfectant wipes): * Use: To effectively disinfect the pre-cleaned surfaces, use a fresh wipe or turn the wipe over to the clean side to thoroughly wet the surfaces to remain wet for the appropriate time indicated for the purpose intended. Allow 2 (two) minute contact time. (Note: The facility's policy referenced CDC.) 9. Observation on 03/06/18 at 9:20 AM, after Patient #19's ultrasound, showed Staff G wiped the foot end of the exam table with a McKesson disinfectant wipe, immediately pulled the roll of paper to cover the area that she had wiped, and failed to allow adequate dry time of the disinfectant. 10. During an interview on 03/07/18 at 1:55 PM, Staff H stated that the disinfectant wipes had a two minute dry time. 11. Review of the facility's container of McKesson disinfectant wipes' label showed, "When not in use, keep center cap closed to prevent	L1128		

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L1128	Continued From page 11 evaporation." 12. Review of the facility's container of PDI-Sani Cloth (Manufacturer and brand) disinfectant wipes' label showed, "Replace lid." 13. Review of the facility's "Infection Prevention Manual" policy titled, "Cleaning, Disinfection and Sterilization," dated 09/05/17, showed: - Germicidal wipes (disinfectant wipes): * Preparation: To start feed, remove cover and discard seal. From the center of the pipe roll, pull up a wipe corner, twist it into a point and thread it though [sic] the hole located on the container cover. Pull through about one inch. Replace cover. Pull out first wipe and tear off at an angle. Remaining wipes feed automatically, ready for the next use. When not in use, keep center cap closed to prevent evaporation. 14. Observation on 03/06/18 at 9:20 AM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff G had failed to close the caps of the containers. 15. Observation on 03/06/18 at 9:30 AM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff I had failed to close the caps of the containers. 16. Observation on 03/06/18 at 9:44 AM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff I had	L1128		

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L1128	Continued From page 12 failed to close the caps of the containers. 17. Observation on 03/06/18 at 2:20 PM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff I had failed to close the caps of the containers. 18. During an interview on 03/07/18 at 1:55 PM, Staff H stated that the containers of disinfectant wipes should have been closed when not in use. 19. Review of the CDC and the HICPAC, "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2008, showed: - Some items that may come in contact with nonintact skin for a brief period of time (i.e., hydrotherapy tanks, bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants. - Clean housekeeping surfaces (e.g., floors, tabletops) on a regular basis, when spills occur, and when these surfaces are visibly soiled. - Disinfect (or clean) environmental surfaces on a regular basis (e.g., daily, three times per week) and when surfaces are visibly soiled. - Use a one-step process and an EPA-registered hospital disinfectant designed for housekeeping purposes in patient care areas where: * Uncertainty exists about the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or * Uncertainty exists about the presence of multidrug resistant organisms on such surfaces. 20. Review of the facility's "Infection Prevention Manual" policy titled, "Environmental Cleaning of Clinical Care Areas," dated 09/05/17, showed:	L1128		

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L1128	Continued From page 13 - Other patient care areas and environmental surfaces that come in direct contact with patients will be cleaned with a facility-approved, EPA registered disinfectant. - Clean the exam/procedure table: * Clean from top; * Clean exposed frame; * Clean headboard, foot board, bed rails, bed attachments and bed controls; pay particular attention to areas that are visibly soiled and surfaces frequently touched by staff; and * Clean all lower parts. (Note: The facility's policy referenced CDC.) 21. Review of the facility's, "Infection Prevention Manual, policy titled, "Cleaning, Disinfection, and Sterilization," dated 09/05/17, showed: - Clean and disinfect exterior of cabinets and doors; - Clean and disinfect all horizontal surfaces; - Clean all furnishings and horizontal surfaces in the room; and - Report any needed repairs. (Note: The facility's policy referenced CDC.) 22. Review of the facility's document titled, "Environmental Cleaning Schedule for Surgical Services Floor, Weekly, Monthly, Periodically Cleaning," dated 2017, showed: - Clean Medical Supply Room daily (including bins and shelves); - Procedure room cabinets vertical surfaces, tops, and shelves, and under sink cleaned two times week; -Ultrasound rooms, furniture cleaned and disinfected daily, Monday through Friday 23.. Observation on 03/05/18 at 2:00 PM of procedure room #1 showed:	L1128		

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L1128	Continued From page 14 - The top of the emergency box was dusty and left a visible mark when a finger was dragged across the surface; and - The trays inside the emergency box were dusty which left a visible mark when a finger was dragged across the surface. 24. Observation on 03/05/18 at 2:05 PM of procedure room #2 showed: - The upper cabinets had peeling labels and adhesive residue; - The top of a plastic storage box on the counter top was dusty and left a visible mark when a finger was dragged across the surface. 25. Observation on 03/05/18 at 2:10 PM of procedure room #3 showed: - A plastic storage box on the counter with a peeling label; and - The top of the emergency box was dusty and left a visible mark when a finger was dragged across the surface. 26. Observation on 03/05/18 at 2:30 PM of the pre/postoperative area showed inside the cabinet above the sink was a gouged area (approximately three centimeters deep) exposing the particle board or pressed wood, leaving an uncleanable surface. 27. Observation on 03/05/18 at 2:40 PM of the supply room showed a metal storage rack with five pressed wood shelves which were an uncleanable surface. 28. Observation on 03/06/18 at 9:07 AM of the supply room showed a metal storage rack with five pressed wood shelves. During an interview upon the observation Staff L, Flow Coordinator,	L1128		

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L1128	Continued From page 15 stated that they cleaned the pressed wood shelves with Lysol (brand of disinfectant). 29. Observation on 03/06/18 at 2:20 PM in the ultrasound room closest to the laboratory showed the following uncleanable surfaces on the exam table: - An approximately one-inch diameter opening (manufacturer's design for the insertion of a side rail) that was full of white paper; and - Peeling tape and a business card on the side of the table. During an interview upon the observation, Staff I stated that: - She had put tissue in the hole of the exam table to fill it; and - The peeling tape was uncleanable. 30. Observation on 03/06/18 at 2:30 PM of the pre/postoperative area showed inside the cabinet above the sink was a gouged area (approximately three centimeters deep) exposing the particle board or pressed wood, leaving an uncleanable surface. 31. Observation on 03/07/18 at 2:30 PM in the pre/postoperative area storage cabinet in bay #11 showed: - Dust on one side of the cabinet which left a visible mark when a finger was pulled across the surface; - Adhesive residue on the opposite side; and - Dirt and debris on the floor behind the cabinet. 32. During an interview on 03/07/18 at 1:20 PM, Staff H stated that: - The housekeeper cleaned but everyone was responsible to clean their own areas including	L1128		

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L1128	Continued From page 16 counters and cabinets; - The person responsible for the area was responsible to clean the emergency boxes including inside the boxes; - Staff L and the housekeeper were responsible to dust the shelving in the supply room; and - She did not agree that the supply room shelves were uncleanable.	L1128		
L1136	19 CSR 30-30.060(1)(B)(12) The administrator shall be responsible The administrator shall be responsible for ensuring that the provisions of Chapter 188, Regulation of Abortions, RSMo 1986 are adhered to. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to ensure patients were given "medically accurate information that a reasonable patient would consider material to the decision of whether or not to undergo the abortion" with respect to the medical risks of "harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion" for a patient (#22) observed as required by law (Section 188.027.1(1), RSMO). The Abortion Facility does an average of 315 cases per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of Missouri law 188.027.1(1) RSMo, showed: - The physician who is to perform or induce the	L1136		

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L1136	Continued From page 17 abortion, a qualified professional, or the referring physician has informed the woman orally, or reduced to writing, and in person, of the following: --(b) Medically accurate information that a reasonable patient would consider material to the decision of whether or not to undergo the abortion, including: --b. The immediate and long-term medical risks to the woman associated with the proposed abortion method including, but not limited to, infection,hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion. 2. Observation on 03/06/18 at 10:45 AM showed Staff GG, Physician, spoke with Patient #22 and stated that: - She would provide the immediate and long-term risks; - There were known medical risks that she would tell the patient about and then there were medical risks that the state of Missouri would like the patient to believe, but there was "no medical evidence to support" (what the state of Missouri would like the patient to believe); - Patient #22 would be almost 14 weeks gestational age at the time of the (surgical abortion) procedure; - There was a risk of infection, bleeding, and injury to the cervix or uterus; - The medication (to dilate the uterus) given prior to the procedure would cause cramping and bleeding; and - The state of Missouri would like you to believe that the procedure will affect your ability to get pregnant, carry a pregnancy to term, and put you	L1136		

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L1136	Continued From page 18 at risk of psychological problems, but there was "no medical evidence to support" (what the state of Missouri would like the patient to believe). During an interview immediately after the observation, Staff GG stated that she had 70 clients with whom to complete the informed consent process that day (03/06/18). 3. During an interview on 03/07/18 at 8:52 AM, Staff FF, Physician, stated that: - What the abortion facility physicians told the clients was based on studies that they had from all over, particularly European countries; - For most women, the range of emotions was normal and most women could handle those emotions; - Staff FF's thought was to base it on medical evidence and that it felt dishonest if there was no medical evidence; and - While there were studies that showed a link (to the risks described in 188.027 and the written informed consent documentation published by the Department), as physicians they went by the preponderance of evidence. 4. During an interview on 03/07/18 at 4:34 PM, during the survey exit conference, Staff CC, Physician, Medical Director, stated that: - He agreed with Staff GG and Staff FF; and - There was no compelling medical evidence to support all of the risks (as described in 188.027 and in the written informed consent documentation published by the Department). 5. Note: It is medically inaccurate for the physicians to state that there is no medical evidence to support that an abortion poses a risk of harm to subsequent pregnancies or the ability	L1136		

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L1136	Continued From page 19 to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion. For some examples of published evidence, see below: -Swingle HM, Colaizy TT, Zimmerman MB, Morriss FH Jr. Abortion and the risk of subsequent preterm birth: a systematic review with meta-analyses. J. Reprod. Med 2009 Feb; 54: 95-108; -PS Shah, a, b, J Zaoa on behalf of Knowledge Synthesis Group of Determinants of preterm/LBW. Induced termination of pregnancy and low birth weight and preterm birth: a systematic review and meta-analyses births*BJOG 2009; 116: 1425-1442; -Oliver-Williams C, Fleming M, Monteath K, Wood AM, Smith GC. Changes in association between previous therapeutic abortion and preterm birth in Scotland, 1980 to 2008: a historical cohort study. PLoS Med 2013; 10(7): e1001481.doi.10.1371/journal. Pmed 1001481. Epub 2013 July 9; and -Thorp JM Jr, Harmann KE, Shadigan E. Long-term physical and psychological health consequences of induced abortion: review of the evidence. Obstet Gynecol Surv. 2003 Jan; 58(1): 67-79	L1136		
L1163	19 CSR 30-30.060(3)(C) A medical history shall be obtained A medical history shall be obtained and a health assessment including a pelvic examination shall be performed. There must be confirmation of pregnancy by clinical evidence and laboratory	L1163		

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L1163	Continued From page 20 tests. The findings shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's chart. This regulation is not met as evidenced by: Based on policy review, record review, observation, and interview, the facility failed to: - Ensure a pelvic examination (visual and physical examination of a woman's reproductive organs [the vagina, cervix, fallopian tubes, vulva, ovaries, and uterus] for any abnormalities) was completed prior to the procedure for one (#25) of one patient observed and five (#1, #2, #6, #9, and #12) of sixteen patients' medical records reviewed; and - Ensure a physical examination was completed immediately prior to the procedure, in order to evaluate the procedural risks for one (#25) of one patient observed and four (#2, #6, #9, and #12) of sixteen patients' medical records reviewed. The Abortion Facility does an average of 315 procedures per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of the facility's policy titled, "Abortion," dated 09/29/17, showed: - 1.1 Medication Abortion: * Physical Examination must include blood pressure and additional examination as indicated	L1163		

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L1163	Continued From page 21 by history or laboratory findings; and * Bimanual exam (two fingers of one hand are inserted in the vagina and the other hand gently palpates the uterus, cervix and adnexae [the ovaries, fallopian tubes, and the ligaments that hold the uterus in place] to evaluate pregnancy, cysts and/or masses in the ovaries) when indicated (e.g., vaginal bleeding or abdominal/pelvic pain). (Note: The policy did not address completing a physical examination to detect any factors which could influence the choice of the procedure to be performed.) 2. Review of the facility's policy titled, "Abortion," dated 09/29/17, showed: - 1.2 Surgical Abortion: * Physical examination must include a visual exam of the vulva, vagina, and cervix, and a bimanual exam, including estimation of uterine size and position and palpation of the adnexa. 3. Review of Patient #1's medical record, with an admission date of 02/28/18, for a surgical abortion procedure showed the facility failed to document a pelvic examination had been completed. 4. During an interview on 03/06/18 at 9:30 AM, Staff H, Health Center Manager, stated that Patient #1 should have had a pelvic examination but she was not sure why it was not documented in the medical record. 5. Review of Patient #2's medical record, with an admission date of 02/20/18, for a medication abortion (a type of non-surgical procedure in which medication is used to bring about an abortion to end a pregnancy) procedure showed:	L1163		

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L1163	Continued From page 22 - The facility failed to document a pelvic examination had been completed; and - The facility failed to ensure a physical examination to evaluate any factors which could influence the choice of the procedure to be performed was documented prior to the procedure performed. 6. During an interview on 03/06/18 at 11:08 AM, Staff H stated that: - No pelvic examinations were completed for patients that received a medication abortion procedure; - They completed a physical examination that included a heart and lung assessment on patients that received a surgical abortion procedure; - The facility took vital signs (clinical measurements, specifically pulse rate, temperature, respiration rate, and blood pressure, that indicate the state of a patient's essential body functions) but did not complete physical examinations that included a heart and lung assessment on patients that received a medication abortion procedure; and - There was no documentation in the medical record that Patient #2 received a pelvic examination or a physical examination that included a heart and lung assessment. 7. Review of Patient #6's medical record, with an admission date of 01/03/18, for a medication abortion procedure showed: - The facility failed to document a pelvic examination had been completed; and - The facility failed to document a physical examination had been completed prior to the procedure to be performed.	L1163		

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L1163	Continued From page 23 8. Review of Patient #12's medical record, with an admission date of 03/02/17, for a medication abortion procedure, showed: - The facility failed to document a pelvic examination had been completed; and - The facility failed to document a physical examination had been completed prior to the procedure to be performed. 9. During an interview on 03/07/18 at 9:02 AM, Staff H stated that Patient #12 did not have a heart and lung physical examination or a pelvic examination documented in the medical record. 10. Review of Patient #9's medical record, with an admission date of 11/22/17, for a medication abortion procedure, showed: - The facility failed to document a pelvic examination had been completed; and - The facility failed to document a physical examination had been completed prior to the procedure to be performed. 11. During an interview on 03/07/18 at 10:32 AM, Staff H stated that she agreed the medical record for Patient #9 did not contain a pelvic examination or a physical examination. 12. Observation on 03/06/18 at 3:55 PM of Patient #25's medication abortion showed Staff FF, Physician, failed to perform a physical and pelvic examination on the patient. 13. During an interview on 03/06/18 at 4:00 PM, Staff CC, Physician, Medical Director, stated that: - They did not perform a pelvic examination on patients that received medication abortions; - It was not medically necessary to complete a pelvic examination on patients that received a	L1163		

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L1163	Continued From page 24 medication abortion since those patients were given an ultrasound (machine that uses high-frequency sound waves to produce images of structures within the body) to confirm their pregnancy and that the gestation age (term used during pregnancy to describe how far along the pregnancy is. It is measured in weeks, from the first day of the woman's last menstrual cycle to the current date) was less than 10 weeks; - The medical necessity was not there to put anything in a women's vagina when they had the ultrasound confirming the pregnancy; and - There was no need to add the stress and discomfort of a pelvic examination to a patient that was terminating her pregnancy by a medication abortion. 14. During an interview on 03/06/18 at 4:05 PM, Staff FF stated that she did not perform physical or pelvic examinations on medical abortion patients as there was no indication to do so.	L1163		
L1170	19 CSR 30-30.060(3)(J) Each abortion facility shall develop Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following: 1. Completeness of clinical records; 2. Incidence of morbidity and mortality; 3. Intraoperative and postoperative complications;	L1170		

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L1170	Continued From page 25 4. All cases transferred to a hospital; 5. All cases that resulted in a length of stay of more than twelve (12) hours; 6. Errors in diagnosis; 7. Problems in compliance with state and local laws and regulations; and 8. All cases in which the gestational age was determined to be beyond eighteen (18) weeks. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to: - Hold quarterly quality assurance meetings; - Review the quality assurance meeting findings with the governing body quarterly; and - Develop a method to accurately track the in/out time of patients to ensure the time onsite was always less than 12 hours. The Abortion Facility does an average of 315 procedures per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of the facility's policy titled "Patient Services Departmental Clinical Quality Assurance Committee," dated 12/31/16 showed: - PPSLRSWMO (Planned Parenthood St. Louis Region South West Missouri) and Affiliated Corporations has a commitment to providing safe, quality care to patients and has a Clinical Quality Assurance (CQA) Committee that meets quarterly with the goal of improving clinical care and management by identifying, analyzing and monitoring patient service provision for compliance with Missouri and Illinois State Regulations, PPFA and Affiliate Standards and Guidelines and other governing bodies.	L1170		

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L1170	Continued From page 26 - Agenda items include: * Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following: - Completeness of clinical records; - Incidence of morbidity and mortality; - Intraoperative and postoperative complications; - All cases transferred to a hospital; - All cases that resulted in a length of stay of more than twelve (12) hours; - Errors in diagnosis; - Problems in compliance with state and local laws and regulations; - All cases in which the gestational age was determined to be beyond eighteen (18) weeks; and - The quality assurance program must show evidence of action taken as a result of identified problems. - The complication report results are reported at quarterly CQA meetings. 2. Review of the minutes from the CQA meetings for 2017 showed meetings were held on 01/23/17, 05/25/17, and 09/25/17. They failed to meet during the fourth quarter (October, November, December) of the year. Review of the Board of Directors Meeting minutes for 2017 showed CQA meeting minutes were reviewed at the 02/01/17 and 10/11/17 meetings. They failed to review the quality assurance issues during the second quarter and the board did not meet during the third quarter of 2017. Review of the CQA minutes showed they did not address length of stay (if greater than 12 hours) during their meetings.	L1170		

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L1170	Continued From page 27 3. During an interview on 03/07/18 at 9:45 AM, Staff M, Quality Assurance Coordinator, stated that: - The CQA committee only met 3 times last year; - They had a complication report that addressed many of the issues they monitor in QA; - They were not open for over 12 hours a day in 2017; - Their "encounter sheets" document arrival time but not check out times; and - They did not have a system to track patients length of stay.	L1170		

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/05/18 to 03/07/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on federal regulations, state statute, policy review, record review, and interview, the facility failed to: - Reconcile controlled substances ordered with controlled substances received; - Conduct an annual inventory of controlled substances; and - Ensure a Power of Attorney (POA) was obtained authorizing the person designated to order narcotics for the facility and ensure the POA was readily available for inspection. The Abortion Facility does an average of 315 cases per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of the Drug Enforcement Administration (DEA) Regulation 21 Code of Federal Regulations (CFR) 1301.71(a) showed: - All applicants and registrants shall provide	L1111		

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1111	A policy and work practices governing controlled substances will be developed and implemented. The policy and work practice- developed will use the *Bureau of Narcotics and Dangerous Drugs ((BNDD) Missouri Department of Health and Senior Services' Controlled Substance Guidelines for Missouri Practitioner* for guidance and will include: • Identification of the controlled substances in use • Training plan with identification training audience, steps to process, their role and • Who can make purchases and how purchases can be made • Who and how to reconcile purchases • Maintain records in accordance with 19 CSR 30-1.;048(1)(A)-(C) • Maintaining complete and accurate records of receiving and dispensing controlled substances for a period of two years, including maintenance and accuracy of DEA Form 222 • Initial inventory and annual inventory Storage • Documentation in patient record • Disposal and destruction of unwanted controlled substances	5/1/ 18	VP of Patient Services	-For the period May 1 through June 30, 2018 the Director of Quality & Training/designee will conduct a monthly audit for controlled substances that will consist of: Initial inventory of controlled substances, any items received during the one month period, any administered/dispensed, destroyed or outdated and the ending inventory of the controlled substances, to ensure that the ending inventory and actual inventory are the same, a review of the presence and accuracy of the supporting documents including appropriate signatures on the ~~of~~ ordering and receiving (DEA Form 222) documents, and documentation in patient records. Beginning with the annual period starting July 1, 2018 an annual audit will be conducted. Results of the review and audit will be reported to the CQA during the next quarter's meeting	

	• Audit process only staff members ordering controlled substances are individual registrants, so therefore no POAs will be needed.).				
L11-28 L1128 (finding , #3, #4, #9, #15, #16, #17, #18, #24	RHS will ensure the provision and maintenance of a safe environment by conducting a review of earlier training to all staff to reinforce current procedure for: • The standard practice of hand hygiene for all staff • Compliance with product recommendations for product use including dry time • Compliance with manufacturer's recommendations for disinfectant product storage • Maintaining clinical areas and storage areas that are free from dust and debris Review with staff cleaning section of current Infection Prevention Manual of Environmental Cleaning of Clinical Care Area. Review cleaning section of current Environmental Cleaning Schedule for Surgical Services Floor. Review cleaning section of current Infection Prevention Manual of Cleaning, Disinfection, and Sterilization. Review cleaning of emergency boxes inner and outer compartments. Review cleaning of cabinets to ensure they are free from peeling labels and adhesive residue. Ensure cleanable surfaces, cabinets, shelving and	4/30/18	Dir of Quality & Training/designee	Edit Quality Management Monthly Site System review- tool to include; • The standard practice of hand hygiene for all staff • Compliance with product recommendations for product use including dry time • Compliance with manufacturer's recommendations for disinfectant product storage • Maintaining clinical areas and storage areas that are free from dust and debris . Monitoring of environmental cleaning will be done during current established use of documented weekly room cleaning check list and environmental cleaning list for the period 30 days. See above	F3

	equipment: Inspect, repair or replace identified un-cleanable surfaces in the clinical facility for • Cabinet door in the pre/postoperative areas • Metal storage rack in the supply room • Ultrasound room exam table			Results of the review and audit will be reported to the CQA during the next quarter's meeting	
L1170 (Finding #2, 3)	Quarterly quality assurance meetings - RHS will develop a written calendar of set quarterly meeting dates and provide this calendar to Clinical Quality Assurance (CQA) committee members for the remaining 2018 calendar year for meeting dates in April, July, and October. A CQA meeting was conducted January 2018. RHS will ensure that the quarterly quality assurance meetings -include a review of the length of stay for patients during the program review. Revise the current CQA Program Review tool for reporting, monitoring and assessing care to include (on the reporting document) the report of result for the length of stay for patients in the facility for the reporting period. Ensure consistent usage by conducting a Patient Activity Tracker (PAT) training for all staff. RHS will also establish and conduct an audit of the work practice for tracking and reporting patients' length of stay in the facility using the PAT system.	4/30/18	Dir of Quality & Training RHS Health Center Manager (HCM) & Quality Assurance (QA) Coordinator	2018 CQA and the Facility Compliance, Quality Risk Management Committee and Board of Directors Meeting minutes will continue to indicate the current practice of reporting results of quality assurance program review that will include all topics specified in 19 CSR 30-30.060 (3) (J). CQA Committee Members will continue to complete the sign in sheet to indicate meeting attendance. Generate a report of facility length of stay for reporting to CQA Committee, and for monitoring by: -Daily review by RHS HCM -Quarterly Reports generated by Quality Assurance Coordinator for CQA Program Review Audit of staff PAT correct usage: -HCM and Flow Facilitator will conduct daily and weekly review for	F4: 2018 CQA Meeting Sche 2018 Meeting Dates.docx dule

				consistent PAT usage and length of stay within standards <8 hrs during the first month of initiation -QA Coordinator will conduct quarterly audits for consistent PAT usage and length of stay within standards <8 hrs Results of the review and audit will be reported to the CQA during the next quarter's meeting	
L1136	RHS has updated its informed consent process regarding harm to subsequent pregnancies, the ability to carry a subsequent pregnancy to term, and possible adverse psychological effects associated with the abortion. Physicians will read the following script to patients regarding these issues (language taken directly from Missouri's Informed Consent Booklet pages 14-15): "Early abortions that are not complicated by infection do not cause infertility or make it more difficult to carry a later pregnancy to term. Complications associated with an abortion can make it more difficult to become pregnant in the future or carry a pregnancy to term. Because every woman is different, one woman's emotional reaction to an abortion may be different from another's. After an abortion, a woman may have both positive and negative feelings, even at the same time. One woman may feel relief, both that the procedure is over and that she is no longer pregnant.	5/18/18	Medical Director/designee Director of Quality & Training/designee	Participation, understanding and agreement to comply with training will be obtained in writing following training event A random sampling of physician consenting sessions will be monitored during the period 05/18/18 through 6/18/18 to ensure 100% compliance Results of the review and audit will be reported to the CQA during the next quarter's meeting	

	Another woman may feel sad that she was in a position where all of her choices were hard ones. She may feel sad about ending the pregnancy. For a while after the abortion she may feel a sense of emptiness and guilt, wondering whether or not her decision was right. Some women who describe these feelings find that they go away with time. Others find them more difficult to overcome. Talking with a counselor or physician may help a woman consider her decision fully before she takes any action." Physicians will participate in a training to review the updated language and receive instructions for its use.				
L1163	RHS is very concerned that DHSS has cited as a deficiency the fact that RHS does not require patients seeking medication abortion to undergo a pelvic examination. A pelvic examination is an intrusive procedure that is not medically necessary for every patient prior to a medication abortion, nor is it part of the accepted standard of care to perform a pelvic examination on every patient seeking a medication abortion. This one-size-fits-all mandate does not consider whether such an exam is medically indicated and is thus overly broad. PPFA and the National Abortion Federation, the two national organizations that accredit abortion providers, do not require a pelvic exam be performed before every medication abortion. 2018 Clinical Policy Guidelines for Abortion Care, National Abortion Foundation p. 17-19. Similarly,				Documents produced in discovery in Comprehensive Health v. Williams, No. 2:17-cv-4207 (W.D. Mo.). Settlement A  DHSS112517.pdf greement

	ACOG, the leading national organization of obstetricians and gynecologists, issues guidelines for medication abortion. These guidelines also do not require routine pelvic exams for medication abortion patients who have had an ultrasound. Practice Bulletin: Medical Management of First-Trimester Abortion, The American College of Obstetricians and Gynecologists, Number 143, March 2014, Reaffirmed 2016. Instead, the standard of care is to provide a pelvic examination to patients prior to a medication abortion only when such an examination is indicated, for example if the patient is experiencing vaginal bleeding or abdominal/pelvic pain. A pelvic examination can be invasive for patients. In particular, victims of rape, or women who have experienced sexual abuse or molestation or other trauma, may want to avoid further trauma from having instruments or a clinician's fingers placed in their vagina, such as during a pelvic exam. Women with such histories often choose medication abortion precisely to avoid having instruments placed in their vagina. There are serious ethical concerns with requiring patients to undergo intrusive examinations in situations where they are not medically necessary, and women should be able to make their own informed decisions about whether to undergo additional screening procedures that are not medically necessary for the service they are seeking. RHS is surprised that DHSS is now requiring pelvic examinations for all patients seeking medication abortion, since DHSS's historical practices have recognized that these examinations are not				PPKMSignedReleas &SettlementAgreem

	medically necessary. As the attached documents show, DHSS has explicitly overlooked this issue in prior inspections of RHS's facility, and has done so because RHS conducts an ultrasound examination for every patient seeking an abortion, including those seeking a medication abortion, rendering a pelvic examination medically unnecessary. See attached documents, produced in discovery in Comprehensive Health v. Williams, No. 2:17-cv-4207 (W.D. Mo.). In addition, RHS is aware that DHSS has waived the pelvic examination requirement for the abortion provider in Kansas City, which provides only medication abortions. There cannot possibly be a medical justification for requiring women who obtain medication abortions in St. Louis to be subjected to an intrusive and medically unnecessary examination that women in Kansas City receiving the same medical service are permitted to forgo. See attached Settlement Agreement. Given that pelvic examinations are not medically necessary for medication abortion, and DHSS's historical recognition of that fact, RHS requests that DHSS reconsider its position and permit RHS to continue its current practice of providing pelvic examinations to patients seeking medication abortion only when indicated. We would appreciate further opportunity to discuss this matter with the Department. RHS will conduct a heart and lung examination for all abortion patients, including medication abortion patients.	5/18/18			

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MCKESSON

McKesson Medical-Surgical

Order Confirmation #5489421

PO	Order #	Submitted	Lines	Lines B/O	Subtotal*
RHS03262018	**5489421**	**Mar 29, 2018**	**1**	**1**	**$25.10**

Account #54423949
PLANNED PARENTHOOD STLOUIS/RHS

Shipping To #54423949
PLANNED PARENTHOOD STLOUIS/RHS
MON 9-1 WED 12-4 THURS 9-1
4251 FOREST PARK AVE
SAINT LOUIS, MO 63108-2810

Questions? Contact Customer Service @ 866-625-2679

View Order Online

Item #	Description	Mfr #	UOM	Price	Qty	B/O	Total
934340	PLUG, ARMRST F/HI/LOW ACCESS GRAB BAR HOLE	101872	EA/1	$25.10	1	(1)	$25.10
	(Kansas City, MO) Backorder quantity is expected to ship on 4/11/18						

* Subtotals only reflect the initial, estimated cost of order lines, not including tax or additional charges

Questions? Contact Customer Service @ 866-625-2679

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Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired: 1-800-735-2466 VOICE: 1-866-735-2460

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 7, 2018

Janice Thomas, VP of Patient Services
Reproductive Health Services (A001)
4251 Forest Park Ave, St. Louis MO 63108

Re: Plan of Correction for licensure survey Event ID J0ST11, survey date 3/7/2018

Dear Ms. Thomas:

The Department of Health & Senior Services received your facility's Plan of Correction (POC) on 4/20/2018 for deficiencies cited on the 3/7/2018 survey of your abortion facility, along with a minor amendment on 5/2/2018.

The Department **does not** accept the POC as written. See below for items we need additional information or clarification on.

Deficiency L1111 (State and Local laws)

1. Controlled Substance Audits: Please provide a copy of the audit form(s) the facility plans to use during the monitoring and data collection for sustained compliance to ensure controlled substances ordered are reconciled with controlled substances received.
2. Controlled Substances – Power of Attorney (POA): Please provide a copy of the POA for anyone authorized to order Schedule I and II controlled substances on the registrant's behalf.
3. Clarify that the DEA numbers for the physician and Advanced practice nurse are not sufficient as the DEA number is in the facility name and should match the DEA form 222, not the individuals.

Deficiency L1128 (Infection Control & Safe Environment)

1. Please send a copy of the revised Quality Management Monthly Site System review tool.

Deficiency L1136 (Ensuring all aspects of Chapter 188)

1. The POC for this item includes reading directly from a script adapted from the DHSS Informed Consent Booklet regarding risks of abortion. However, the cited deficiency was for providing inaccurate medical information (saying there was "no medical evidence" of certain risks when actually said evidence does exist.) Will the facility's re-training of physicians include specific directions not to negate the proposed script by stating some version of "there is no medical evidence"?
2. For this corrective item, you state the facility will include a random sampling of observations of the physician informed consent process. Could you clarify how many observations will be included and/or whether all physicians performing abortions will be included?

Deficiency L1163 (Medical History and Health Assessment)

1. Pelvic Exam required for medical abortion (MAB) patients:
    a. The regulation requires pelvic exams for all abortions and DHSS is enforcing the regulation as written.
    b. Regarding the 2010 Settlement Agreement with Planned Parenthood of Kansas and Missouri (now Great Plains):
        i. The Settlement Agreement only pertains to the Kansas City and Columbia locations, not the St Louis facility.
        ii. The specific provision for not requiring pelvic exams only includes the Kansas City facility.

2. Physical examination of the heart and lungs for medication abortion (MAB) patients:
    a. How were the staff and physicians educated that the physical examination must be conducted for MAB patients prior to their procedure?
    b. How will the facility monitor to ensure the physical examinations are conducted prior to the medication administration for MAB patients?
    c. What is the frequency and duration of the monitoring to ensure sustained compliance?
    d. Where will this information be reported (CQA?/GB)?

Deficiency Tag L1170 (Quality Assurance Program)

1. This portion of the POC is acceptable as written.

Please respond in writing in regards to the above items within the next seven (7) days. As discussed during the survey, once an acceptable POC has been received, a revisit will be conducted to assure compliance with all applicable rules and statutes. Per 19 CSR 30-30.050(2)(G), a license shall not be issued by the DHSS until an abortion facility is in compliance with all requirements of the applicable rules. **Your facility's abortion facility license expires 5/31/2018.** If you have additional questions do not hesitate to contact our office.

Sincerely,

John Langston

John Langston, Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158
Email: BAC@health.mo.gov

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Reproductive Health Services of Planned Parenthood of the St. Louis Region

4251 Forest Park Avenue
St. Louis, MO 63108

p: 314.531.7526 | f: 314.531.9730
www.plannedparenthood.org/stlouis

May 10, 2018

John Langston, Administrator
Bureau of Ambulatory Care
920 Wildwood
Jefferson City, MO 65102

Re: Plan of Correction for Licensure Survey Event ID J0ST11, Survey Date 3/7/2018

Dear Mr. Langston:

Reproductive Health Services of Planned Parenthood received your responses to our plan of correction for the survey dated 3/7/2018, on 05/07/2018. In your response you identified specific areas for additional information or clarification. Following are the clarifications and/or additional information requested in **red:**

Deficiency L1111 (State and Local laws)

1. Controlled Substance Audits: Please provide a copy of the audit form(s) the facility plans to use during the monitoring and data collection for sustained compliance to ensure controlled substances ordered are reconciled with controlled substances received. **See attached Item #1**
2. Controlled Substances – Power of Attorney (POA): Please provide a copy of the POA for anyone authorized to order Schedule I and II controlled substances on the registrant's behalf. **Reproductive Health Services does not provide Schedule I controlled substances. The POA for schedule II controlled substances is attached. See attached Item #2**
3. Clarify that the DEA numbers for the physician and advanced practice nurse are not sufficient as the DEA number is in the facility name and should match the DEA form 222, not the individuals. **Reproductive Health Services is using a facility DEA that matches the DEA form 222 and has verified that the appropriate facility DEA is on file with vendors. See attached Item #3**

Deficiency L1128 (Infection Control & Safe Environment)

1. Please send a copy of the revised Quality Management Monthly Site System review tool. **See attached Item #4**

Deficiency L1136 (Ensuring all aspects of Chapter 188)

1. The POC for this item includes reading directly from a script adapted from the DHSS Informed Consent Booklet regarding risks of abortion. However, the cited deficiency was for providing inaccurate medical information (saying there was "no medical evidence" of certain risks when actually said evidence does exist.) Will the facility's re-training of physicians include specific directions not to negate the proposed script by stating some version of "there is no medical evidence"?
The re-training with RHS physicians will include directions not to negate the information in the proposed script, including by stating 'there is no medical evidence' to support the information.

2. For this corrective item, you state the facility will include a random sampling of observations of the physician informed consent process. Could you clarify how many observations will be included and/or whether all physicians performing abortions will be included?
All physicians will be observed. The selection of the physician will be random and we will perform a minimum of 11 observations.

Deficiency L1163 (Medical History and Health Assessment)

1. Pelvic Exam required for medical abortion (MAB) patients:
   a. The regulation requires pelvic exams for all abortions and DHSS is enforcing the regulation as written. Reproductive Health Services
   b. Regarding the 2010 Settlement Agreement with Planned Parenthood of Kansas and Missouri (now Great Plains):
      i. The Settlement Agreement only pertains to the Kansas City and Columbia locations, not the St Louis facility.
      ii. The specific provision for not requiring pelvic exams only includes the Kansas City facility. **With the submission of this document, all patients receiving an abortion at Reproductive Health Services in St. Louis will receive a pelvic exam prior to the abortion procedure.**

2. Physical examination of the heart and lungs for medication abortion (MAB) patients:
   a. How were the staff and physicians educated that the physical examination must be conducted for MAB patients prior to their procedure?
   The communication was provided to all Reproductive Health Service physician staff by the medical director and to other staff by the Health Center Manager.
   b. How will the facility monitor to ensure the physical examinations are conducted prior to the medication administration for MAB patients?
   The physical examination will be documented in the electronic medical record. Each patient's record is reviewed prior to the procedure. The review will now include the presence of a documented physical exam.
   c. What is the frequency and duration of the monitoring to ensure sustained compliance? The monitoring will be done as described above and will occur with all MAB patients. **The inclusion of documentation of a physical examination for MAB patients will become a part of the Reproductive Health Services process and will remain in place until such time as a process change is required.**
   d. Where will this information be reported (CQA?/GB)?
   Information regarding physical examinations will be reported during CQA.

Deficiency Tag L1170 (Quality Assurance Program)

1. This portion of the POC is acceptable as written.

Please acknowledge receipt of our responses. We look forward to a prompt review and scheduling of any required on-site reviews to ensure there is no delay is the issuance of our license expiring on May 31, 2018.

Sincerely,

Janice Thomas

Janice Thomas
Administrator
Reproductive Health Services
4251 Forest Park Avenue St. Louis, MO 63108

Attachments:

Item #1 – DEA Audit Form

Item #2 – POA for Controlled Substances

Item #3- RHS DEA license & BNDD

Item #4 - Quality Management Monthly Site System review tool

Americans United for Life

Reproductive Health Services of Planned Parenthood of the St. Louis Region

CONTROLLED SUBSTANCES AUDIT CHECKLIST

(For audit of Schedule 2 Controlled Substances- Affiliate does not purchase or administer Schedule III-V drugs)

DATE: _____ **DEA REGISTRANT #:** _____ **AUDITORS:** _____

_____

APPLICABLE SECTIONS	OBSERVATION	YES	NO	COMMENTS
Registration	• Is the original signed POA letter on file? • Is there a current State registration on site?	☐	☐	
Security	• Are the physical security controls for the storage area; • Securely locked, substantially constructed cabinet or safe • Access to the storage area restricted to persons specifically authorized to handle controlled substances (including restricted number of keys and/or passwords) • Controlled substances stored in refrigerators are also locked	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
	• Is there "Limited Access" restricted to person specifically authorized to handle the controlled substances?	☐	☐	
Records	• Are records on site for the last two years; • Initial inventory, • Dispensing log, • Receipts • Lost/contamination/destruction	☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐	
	• Annual inventory, • Does the inventory form reflect all controlled substances on site? • Does the inventory form identify when inventory was taken; opening of the business day or the closing of the business day?	☐	☐	
Order Forms	• Are unexecuted DEA 222 forms secured in a locked or restricted access area? Describe controls in place from facility entrance down to locked drawers with numbers of personnel with access.	☐	☐	
	• Are there receipt records that do not have an accompanying DEA 222 form? If so, substance, quantity, strength specify compound, date, DEA 222 number, quantity of compound, etc.	☐	☐	
	• Are any of the DEA 222 forms signed by someone other than an authorized POA? Ensure the POA signing the DEA 222 forms is authorized by the current DEA Registrant. Also check if any revoked POA signed a DEA 222 form past the date of revocation.	☐	☐	
	• Are the DEA 222 forms executed in compliance with Part 1305.06? If not, specify non-compliant issues.	☐	☐	

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APPLICABLE SECTIONS	OBSERVATIONS	YES	NO	COMMENTS
	• Note the total number of voided DEA 222 forms; specify in the comments section.	☐	☐	
	• Note the total number of DEA 222 forms with notes/ memos to the files that clarify adjustments to shipped quantities (e.g., received too much).	☐	☐	
Destruction and/or Disposal	• Review destruction records (DEA 41 forms) for the last two years	☐	☐	
	• If on-site destruction is performed, confirm that DEA authorization is in place (e.g., letter in the files).	☐	☐	
	• If off-site destruction (e.g., transport to incinerator) is performed, have the DEA stipulations been met? For example, if DEA requires 1 month prior notice, is the letter notifying DEA of the proposed destruction date in accordance with those conditions? If conditions are not met, specify in comments section.	☐	☐	
SOPs	• Are the SOPs being followed with respect to continuing records (e.g., all completed for all transactions)? If not, specify non-compliant situations.	☐	☐	
	• Are the SOPs being followed with respect to the handling and storage of CS materials in the labs and/or manufacturing environments? If not, specify non-compliant situations (e.g., in-process storage of manufacturing materials with inadequate security safeguards).	☐	☐	
	• Are the SOPs being followed with respect to routine inspections and in-house audits? If not, specify non-compliant situations (e.g., quarterly or annual audits overdue).	☐	☐	
Loss/ Diversion Reports	• Are there any documented situations of unaccounted losses or potential diversion of product that were not reported to DEA? If so, specify situation and reasons why.	☐	☐	
	• Are the accountability systems *in toto* sufficient to quickly detect loss or diversion? If not, please specify potential areas for improvement.	☐	☐	

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Reproductive Health Services of Planned Parenthood of the St. Louis Region

4251 Forest Park Avenue
St. Louis, MO 63108

p: 314.531.7526 | f: 314.531.9730
www.plannedparenthood.org/stlouis

May 9, 2018

Reproductive Health Services
4251 Forest Park Avenue
St. Louis, MO 63108

DEA registration number: BR4864787

I, Janice Thomas the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint ____ Rhonda Henderson my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

(Signature of person granting power) Janice Thomas

I, Rhonda Henderson hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact) Rhonda Henderson

Witnesses:

1. [illegible]

2. Cathy Williams

Signed and dated on the 9 day of May (year), at 2018.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

(Signature of person revoking power)

Witnesses:

1. _____

2. _____

Signed and dated on the ____ day of ____, (year), at ____.

Americans United for Life

10021268. 2/001253

590/656 1: 3
REPRODUCTIVE HLTH SRVES OF PL
PARENTHOOD OF THE ST LOUIS REG
4251 FOREST PARK AVE
SAINT LOUIS, MO 63108-0000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR4864787	04-30-2020	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	HOSPITAL/CLINIC	03-14-2017

REPRODUCTIVE HLTH SRVES OF PL
PARENTHOOD OF THE ST LOUIS REG
4251 FOREST PARK AVE
SAINT LOUIS, MO 63108-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR4864787	04-30-2020	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	HOSPITAL/CLINIC	03-14-2017

REPRODUCTIVE HLTH SRVES OF PL
PARENTHOOD OF THE ST LOUIS REG
4251 FOREST PARK AVE
SAINT LOUIS, MO 63108-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	REPRODUCTIVE HEALTH SERVICES (REPRODUCTIVE HEALTH SERVICES)
BNDD Number:	30350
Description:	AMBULATORY SURGICAL CENTER
Street Address:	4251 FOREST PARK AVE
City/State/Zip:	ST LOUIS, MO 63108.2810
Phone Number:	314-531-7526
Registration Effective:	4/2/2018
Registration Expires:	5/31/2019
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	4/2/2018

Reproductive Health Services of Planned Parenthood of the St. Louis Region
4251 Forest Park Avenue, 63108 314-531-7526

QM Monthly Site System Review **Month**_____/_____

To be completed monthly by Surgical Services Manager/Delegate

Site_____ **Auditor**_____

<table>
<tr><th>Date</th><th>System Reviewed
(During Clinical Operations Including Patient Care/Interactions)</th><th>Guidelines Met</th><th>Guidelines Not Met</th></tr>
<tr><td></td><td>Exit and pathways in the surgical center are clear</td><td></td><td></td></tr>
<tr><td></td><td>Ceiling vents clear of dust and debris</td><td></td><td></td></tr>
<tr><td></td><td>Computer passwords are secured and not visible</td><td></td><td></td></tr>
<tr><td></td><td>Universal Precautions used by all staff (Including before & after pt contact)
<table><tr><th>{Initials of staff observed}</th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab staff { } { }</td><td></td><td></td></tr><tr><td>Sono staff { } { }</td><td></td><td></td></tr><tr><td>Procedure Room staff { } { }</td><td></td><td></td></tr><tr><td>Decontamination staff { } { }</td><td></td><td></td></tr><tr><td>Sterilization staff { } { }</td><td></td><td></td></tr><tr><td>Environmental Services staff { } { }</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Personal Protective Equipment available & appropriately used (i.e. masks, lab coats, gloves in various sizes, face shield, vinyl gloves, utility gloves) as appropriate for job duty
<table><tr><th>{Initials of staff observed}</th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab staff { } { }</td><td></td><td></td></tr><tr><td>Sono staff { } { }</td><td></td><td></td></tr><tr><td>Procedure Room staff { } { }</td><td></td><td></td></tr><tr><td>Decontamination staff { } { }</td><td></td><td></td></tr><tr><td>Sterilization staff { } { }</td><td></td><td></td></tr><tr><td>Environmental Services staff { } { }</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Steps to follow when an accident occurs involving workers compensation is posted and forms readily available for staff</td><td></td><td></td></tr>
<tr><td></td><td>Emergency equipment audited by nursing supervisor(_____) (initials)
Resuscitative equipment First Aid Kit Spill Kit/Supplies
Flashlights and back up lighting operable Ammonia Capsules Defibrillator
Exit lighting operable Cart with emergency supplies & weekly checklist current</td><td></td><td></td></tr>
<tr><td></td><td>Fire Extinguishers easily accessible, charged, inspection current for monthly and annually</td><td></td><td></td></tr>
<tr><td></td><td>MSDS Log current with supplies that are used in the health center: randomly checked the following area & supplies for MSDS sheets
<table><tr><th>Area</th><th>Supply Name</th><th>MSDS—yes/no</th></tr><tr><td>Lab</td><td></td><td></td></tr><tr><td>Sono</td><td></td><td></td></tr><tr><td>Procedure</td><td></td><td></td></tr><tr><td>Decon/Steriliz</td><td></td><td></td></tr><tr><td>Enviro Services</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
</table>

Americans United for Life

<table>
<tr><th>Date</th><th>System Reviewed
(During Clinical Operations Including Patient Care/Interactions)</th><th>Guidelines Met</th><th>Guidelines Not Met</th></tr>
<tr><td></td><td>Environmental Care: Rooms & Equipment Clean, free from dust & debris
-Overall cleanliness of area (floors, counters, shelving, drawers, cabinets)
-Smooth cleanable surfaces
-Regular and biohazard trash not over flowing containers
-Disinfectant solution available
-Surface decontamination performed per infection control protocol
-Equipment clean
-Carts clean
-Segregation of clean/sterile items
-Shelving for sterile instruments clean and dry with protective barrier on bottom shelf
-Functional work areas physically separated by wall/closed sliding door during instrument reprocessing area (in decontamination area)
-Corrugated boxes not in clinical care/storage areas
<table><tr><th></th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab Area</td><td></td><td></td></tr><tr><td>Sono rooms</td><td></td><td></td></tr><tr><td>Procedure rooms</td><td></td><td></td></tr><tr><td>Recovery room</td><td></td><td></td></tr><tr><td>Decontamination room</td><td></td><td></td></tr><tr><td>Sterilization room</td><td></td><td></td></tr><tr><td>Storage rooms</td><td></td><td></td></tr><tr><td>Work stations</td><td></td><td></td></tr><tr><td>Education/Interview rooms</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Staff use protective equipment for patient interactions, cleaning of rooms and equipment management as necessary</td><td></td><td></td></tr>
<tr><td></td><td>All specimens labeled, handled appropriately and staff follows general packaging requirements</td><td></td><td></td></tr>
<tr><td></td><td>Disposed specimen containers with PHI de-identified before disposal</td><td></td><td></td></tr>
<tr><td></td><td>Single use suction tubing discarded after each procedure</td><td></td><td></td></tr>
<tr><td></td><td>Decontamination receiving and clean/sterilized items separated</td><td></td><td></td></tr>
<tr><td></td><td>Checklist completed by assigned staff
-Daily lab refrig temp & cleaning documented -Decontamination & Sterilization Procedures documented -Sterilizer indicator with each autoclave batch -Weekly & Monthly autoclave cleaning -Daily Spore Testing with each load documented for each autoclave machine</td><td></td><td></td></tr>
<tr><td></td><td>Inventory & Control Logs current and completed</td><td></td><td></td></tr>
<tr><td></td><td>No expired medication/supplies/merchandise on shelves or in clinical area
<table><tr><th></th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab</td><td></td><td></td></tr><tr><td>Sono rooms</td><td></td><td></td></tr><tr><td>Procedure rooms</td><td></td><td></td></tr><tr><td>Recovery room</td><td></td><td></td></tr><tr><td>Decontamination room</td><td></td><td></td></tr><tr><td>Sterilization room</td><td></td><td></td></tr><tr><td>Storage areas</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Multi-dose vials dated when opened: documentation of date/time opened & staff initials & discarded within 28 days</td><td></td><td></td></tr>
<tr><td></td><td>Multi-dose vials restricted to centralized area of designated nurses station
-Prepared medication syringes in drawer labeled "injectable" medicine at Nurses' Medication Prep Station in recovery area</td><td></td><td></td></tr>
</table>

Date	System Reviewed	Guidelines Met	Guidelines Not Met
	Controlled substance log has appropriate documentation completed when applicable		
	Sharp Collectors placed on shelves or in wall brackets Lab area: Compliant ____ Non-Compliant ____ Sono room: Compliant ____ Non-Compliant ____ Procedure room: Compliant ____ Non-Compliant ____ Recovery room: Compliant ____ Non-Compliant ____ Decontamination room: Compliant ____ Non-Compliant ____ Sterilization room: Compliant ____ Non-Compliant ____		
	Potentially infectious waste(i.e. blood soaked products, IV tubing with blood, tissue, POC) **in appropriate containers**		
	Disposal of sharps (i.e. needles, lancets, capillary tubes syringes with needles, used microscopic slides & cover slips, etc.) **in appropriate sharp containers**		
	Unexpired cleaning supplies & equipment accessible to staff		
	Clinic Procedure and Laboratory Practices Manual available to staff **Staff can identify how to access**		
	Manufacturer's equipment guidelines for operational usage on site for: ▪ **Laboratory Equipment** ▪ **Decontamination & Sterilization Equipment**		
	Proficiency Log in place for all staff, including staff whose job duties began in current month		
	Workstations free of hazards		

Comments/Corrective Actions:

Manager of Surgical Services/Delegate Review Signature:

Name _____ **Title** _____ **Date** _____

At completion of audit and review by Manger of Surgical Services, form submitted to Director of Quality and Training.

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 30, 2018

Janice Thomas
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Revisit Survey***

Dear Janice Thomas:

Please see attached results of the recent follow-up survey of ***May 29, 2018***. This relates to the Licensure survey conducted ***March 7, 2018***. Your facility is now in compliance with the Licensure requirements for Abortion Facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 05/29/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced state licensure revisit survey was conducted on 05/29/18. The facility was found to be in compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and Chapter 188, RSMo (Regulation of Abortions).	{L 000}		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 03/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	**4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 03/06/18 sporadically through 03/19/18 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00140153 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

March 21, 2018

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint #MO00140153***

Dear Mary Kogut:

The results of the recent survey conducted at your facility on ***March 19, 2018*** indicate that your facility is in compliance with the State Licensure regulations for abortion facilities.
Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

January 4, 2019

Cathy Williams, SPHR, SHRM-SCP
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00151249***

Dear Cathy Williams:

The results of the recent complaint survey conducted at your facility on ***January 3, 2019*** indicate that your facility is in compliance with the State Licensure regulations for abortion centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-1588.

Respectfully,

Melinda Laughlin RN,BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 01/03/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments As directed by the Bureau of Ambulatory Care, an on-site, unannounced allegation survey was conducted on 01/03/19 for complaint #MO00151249. The allegation was found to be unsubstantiated with no deficiencies.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

February 27, 2019

Janice Thomas
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00152740***

Dear Janice Thomas:

The results of the recent complaint survey conducted at your facility on ***February 11, 2019*** indicate that your facility is in compliance with the State Licensure regulations for abortion centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-1588.

Respectfully,

Melinda Laughlin RN,BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 02/11/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments As directed by the Bureau of Ambulatory Care, an on-site, unannounced allegation survey was conducted on 02/11/19 for complaint #MO00152740. The allegation was found to be unsubstantiated with no deficiencies.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

March 27, 2019

Kawanna Shannon
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Kawanna Shannon:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings (deficiencies) of the survey conducted on ***03/13/2019*** in connection with the Licensure requirements as they pertain to ambulatory surgical centers in Missouri. Please submit a Plan of Correction (POC) stating how you will correct the cited deficiencies. This POC must be submitted within ten (10) calendar days of the date this letter and SOD is received by your facility.

An acceptable plan of correction must contain the following elements:

1. Address each deficiency individually, unless both State and Federal regulations have been cited. For example, A0405 and L1236 often address the same concerns. If the deficiency statement is identical, you may combine the citations and state one Plan of Correction.
2. The plan should state how you will improve the process that led to the deficiency cited. State each component, as indicated. For example, write facility policy, train staff on new process, etc.
3. The plan must include the monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected and /or in compliance with the regulatory requirements. The Plan must include frequency and length of monitoring and tracking procedures to ensure the plan of correction is effective.
4. The plan must include a date when each deficiency will be/has been corrected or completed. In general, we would expect the facility to have a corrective action fully implemented no later than 45 days after the Statement of Deficiencies was received. This date must include when the facility will be in full compliance.
5. Should you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include the expected completion date(s) for each phase. If the phased POC is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.
6. The plan must include the title of the person responsible for implementing and monitoring the plan of correction for each deficiency, and must state how the stated improvement actions will be incorporated into your Quality Assessment and Performance Improvement (QAPI) Program to reduce the likelihood of the deficient practice reoccurring.
7. The first page of the Form 2567 **for each set of regulations cited** must be signed and dated in the block labeled "Facility Representative's Signature."

Americans United for Life

Even though the deficiency may have been corrected before a Plan of Correction is returned to this office, the plan must be outlined as stated above. The statement "corrected" or "completed" is not an acceptable response. Your POC must specify how these deficiencies were corrected and the date of correction.

Please retain a copy of this letter and the SOD for your reference. We welcome any questions at (573) 751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/13/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/11/19 to 03/13/19 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		

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L 069	Continued From page 1 2. Review of the facility's records of fire drills showed that the most recent fire drill occurred on 11/30/18 and the previous drill occurred on 06/02/17. (Note: The time between drills was more than 12 months). The list of staff on the drill from 11/30/18 showed 30 names and 10 were indicated as having been part of the drill. 3. During an interview on 03/11/19 at 4:15 PM, Staff N, Clinical Quality Improvement Manager, stated that she did not know why the fire drills were more than 12 months apart and that no physicians were listed as participating as there were none onsite that day.	L 069		
L1069	19 CSR 30-30.060(1)(A)(1) The governing body shall have full legal The governing body shall have full legal responsibility for determining, implementing, and monitoring policies governing a facility's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment and in accordance with all legal requirements and standards of care. This regulation is not met as evidenced by: Based on record review the facility failed to ensure all policies were written to maintain compliance with all regulatory requirements for obtaining a complete medical history to include a pelvic examination. Findings included: 1. Licensure regulations at 19 CSR 30-30.060 (2)(D) require a written medical history shall be obtained for each patient. A health assessment	L1069		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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L1069	Continued From page 2 including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Training's Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical abortion when medically indicated - current practice.	L1069		
L1076	19 CSR 30-30.060(1)(A)(8) The governing body, ensure abortion facility The governing body, through the administrator, shall ensure that the abortion facility abides by all applicable state and federal laws and regulations. This shall include, but not be limited to, compliance with Chapter 188, RSMo. This regulation is not met as evidenced by:	L1076		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1076	Continued From page 3 Based on policy review, record review and interview, the facility failed to ensure the physician who obtained the informed consent was the physician who performed or induced the abortion for two (#7 and #10) of 10 patients' abortion medical records reviewed. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. The physician who is to perform or induce the abortion shall provide the information required in section 188.027.6, RSMo, orally and in person to the patient at least seventy-two (72) hours before the abortion. 2. Review of the facility's policy titled, "Consent and Informed Consent," dated 06/16, showed per Missouri SB (Senate Bill) 793 and SB5 ALL women who request an abortion in Missouri must meet with a Qualified Health Professional and the physician who will provide the abortion procedure for consultation at least 72 hours prior to an abortion procedure (or informed consent may be given by physician only). 3. Review of Patient #7's medical record showed: - On 11/15/18, Staff GG, Medical Doctor (MD), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion." - On 11/20/18, Staff AA, MD, administered Mifepristone (stops the pregnancy from growing and is the first of two medications administered in a medication-induced abortion). 4. During an interview on 03/12/19 at 1:04 PM,	L1076		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1076	Continued From page 4 Staff A, Director of Surgical Services, stated that: - Staff AA was a fellow (physician who has completed their residency and elects to complete further training in a specialty) who worked with Staff GG. - The Mifepristone agreement (medication agreement form signed by the patient and provider [physician] that explains that the medications will end the pregnancy, what to expect, and directions) was signed by the patient and Staff AA. 5. Review of Patient #10's medical record showed: - On 08/29/18, Staff FF, Doctor of Osteopathic Medicine (physician whose training focused on emphasizing a whole-person approach to treatment and care), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion." - On 09/05/18, Staff AA attempted a surgical abortion, which was unsuccessful. - On 09/05/18, Staff AA administered Mifepristone. - A separate document generated by Staff FF that included: * "I was present for the procedure and agree with the treatment and follow up plan(s)." * "TV (Trans-vaginal) U/S (ultrasound) was able to confirm the path, but given the unique position of the uterus and patient's discomfort, coupled with early gestational age, we opted to stop the SAB (surgical abortion) and proceed with MAB (medical abortion)." 6. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that: - The supervising physician was responsible for	L1076		

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L1076	Continued From page 5 care of the patient; - The supervising physician for Patient #7 was Staff GG; - Staff GG did not complete a supervisory note for Patient #7; - Staff AA could administer the Mifepristone without the supervisory physician in the room; - Staff GG was in the room during the surgical abortion attempt on Patient #7 (performed by Staff AA); and - The supervising physician for Patient #10 was Staff FF.	L1076		
L1103	19 CSR 30-30.060(2)(D) A written medical history shall be obtained A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to perform the pelvic examination at a time that could influence the choice of the planned procedure and pre-operative management for nine (#1, #2, #3, #4, #5, #6, #7, #8, and #10) of nine patients' abortion medical records reviewed.	L1103		

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L1103	Continued From page 6 The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. 188.027 states that Consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion: 1(f)- the physician who is to perform or induce the abortion, a qualified professional, or the referring physician informs the woman of the gestational age of the unborn child at the time the abortion is to be performed or induced. 30-30.060 (D) A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Trainings Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical	L1103		

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L1103	Continued From page 7 abortion when medically indicated - current practice. 3. Review of medical records for Patient #1, #2, #3, #4, #5, #6, and #8 with admission dates ranging from 11/17/18 to 02/23/19 for a surgical abortion showed documentation included findings from a pelvic examination, but the date and time of the pelvic examination were not documented. 4. Review of Patient #7's medical record, dated 11/20/18, showed the patient was admitted for a surgical abortion. The physician's undated and untimed note of the pelvic examination included, "Exam limited by body habitus." A medical record entry, dated 11/20/18 at 1:40 PM, showed Staff B, Registered Nurse, documented, "Per (Staff GG, Medical Doctor [MD]) they were unable to perform in clinic procedure (surgical abortion) so patient will proceed with medication abortion." 5. Review of Patient #10's medical record, dated 09/05/18, showed the patient was admitted for a surgical abortion. Documentation included findings from a pelvic examination, but the date and time of the pelvic examination were not documented. (Note: The surgical abortion was unsuccessful so the plan changed to a medication-induced abortion.) 6. During an interview on 03/13/19 at 11:50 AM, Staff A, Director of Surgical Services, stated that: - The pelvic exam was done after the consenting process and pre-operative phase; - Pelvic exams were done right after the time out (intentional pause immediately before starting the surgical procedure when a final verification is made to confirm the correct patient, surgery, side, implant, and any special requirements);	L1103		

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L1103	Continued From page 8 - Right after the pelvic exam, medications were given and then the procedure was completed; and - The medical records did not include the date and time of the pelvic exam. 7. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that: - Routinely, they performed the time out, the pelvic exam, administered the medication, and then performed the procedure. - They did the pelvic exam before going into the uterus.	L1103		
L1116	19 CSR 30-30.060(2)(N) Facilities performing surgical,emergency drug Facilities performing surgical procedures shall have emergency drugs, oxygen, and intravenous fluids in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine, and endotracheal equipment shall be located in the clinical area for immediate access. This regulation is not met as evidenced by: Based on state statute, nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained the necessary endotracheal equipment (equipment used to provide respiration when the patient is unable to breath for themselves) readily available to manage a respiratory emergency; - Staff were familiar with the location and operation of emergency equipment; and - Policies were developed to ensure staff orientation and knowledge validation for the	L1116		

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L1116	Continued From page 9 location and use of emergency supplies; The Abortion Facility does an average of 216 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the 2011 Missouri Revised Statutes TITLE XII PUBLIC HEALTH AND WELFARE Chapter 197 Medical Treatment Facility Licenses Section 197.230 showed: - The department of health and senior services shall make, or cause to be made, such inspections and investigations as it deems necessary. The department may delegate its powers and duties to investigate and inspect ambulatory surgical centers or abortion facilities to an official of a political subdivision having a population of at least four hundred fifty thousand if such political subdivision is deemed qualified by the department to inspect and investigate ambulatory surgical centers. The official so designated shall submit a written report of his or her findings to the department and the department may accept the recommendations of such official if it determines that the facility inspected meets minimum standards established pursuant to sections 197.200 to 197.240. - In the case of any abortion facility, the department shall make or cause to be made an unannounced on-site inspection and investigation at least annually. Such on-site inspection and investigation shall include, but not be limited to, the following areas: (1) Compliance with all statutory and regulatory requirements for an abortion facility, including requirements that the facility maintain adequate staffing and equipment to respond to medical emergencies.	L1116		

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L1116	Continued From page 10 2. Review of the Association of PeriOperative Registered Nurses "Guideline for Care of the Patient Receiving Moderate Sedation/Analgesia (a condition in which the patient exhibits a mildly depressed level of consciousness and an altered perception of pain but retains the ability to respond appropriately to verbal or tactile stimulation)," dated 2018, showed: - Recommendation III.c.4. * Monitoring equipment (e.g., pulse oximetry (device that measures the oxygen saturation of arterial blood), Electrocardiogram (ECG - measures electrical activity all over the heart), capnography (the monitoring of the concentration carbon dioxide in the respiratory gases), blood pressure measurement devices, oxygen source, masks and cannulas, suction source, tubing, and tips, and oral and nasal [through the nose] airways) should be working properly, and immediately available in the room where the procedure is being performed. - Recommendation III.e. * Emergency resuscitation equipment and supplies should be immediately available in every location in which moderate sedation is administered. - Recommendation III.e.1. * Emergency equipment and supplies should include: Airway and ventilatory equipment (e.g., laryngoscopes (a diagnostic tool with a blade, light, and mirrors, used to examine the larynx [hollow organ in the throat that forms an air passage to the lungs]), endotracheal tubes (ETT- a breathing tube inserted into the airway to keep the airway open), laryngeal mask airway (LMA - a medical device that keeps a patient's airway open during anesthesia or unconsciousness),	L1116		

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L1116	Continued From page 11 oral and nasal airways; 3. Review of the facility's policy titled, "Emergency Response Protocol and Procedure for Emergency Transfer of Patients in Life Threatening Situations," dated 02/19, showed: - When an emergency is recognized by staff they will respond to the patient in crisis and notify physician and Registered Nurse (RN)/Licensed Practical Nurse (LPN). - Basic Life Support (BLS - a level of medical care which is used for victims of life-threatening illnesses or injuries until they can be given full medical care) services and supportive care will be started as indicated. - Treating physician will direct patient care and designate team members to carry out tasks as necessary. * Be sure to start with the ABCs (Airway, Breathing, Circulation). - RN/LPN who comes to the room should assess ABCs and should ask treating physician for report regarding any other equipment (e.g. intravenous (small catheter inserted into a vein for administering medication and fluid) access, oxygen, and ultrasound) or medications needed. (Note: The policy failed to identify the emergency equipment necessary to treat seizures, bleedings, anaphylactic shock, respiratory arrest, and cardiac arrest and other life threatening emergencies and failed to address the need for staff orientation and training on the locations and operation of emergency equipment.) 4. Review of the facility's undated document titled, "Emergency Box: Medication and Supplies," showed the emergency box checklist failed to include suction equipment, i.e., suction device (plastic suction tip used to suction	L1116		

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L1116	Continued From page 12 secretions from the mouth and throat) and endotracheal equipment (equipment used to manage an open airway, i.e., endotracheal tubes, endotracheal tube introducers [device used to assist in obtaining an airway] and laryngoscope handle and blades). 5. Review of the facility's undated checklist titled, "Quality Management (QM) Site System Review," showed: - The document was to be completed monthly by the Surgical Services Manager/Delegate and included: - Emergency Equipment * Audited by nursing supervisor (blank for initials). * Resuscitative equipment; and * Cart with emergency supplies & weekly checklist current. (Note: The checklist failed to contain a list of specific emergency or resuscitative equipment to be checked.) 6. Observation on 03/11/19 at approximately 1:45 PM showed: - A portable suction machine in supply storage room #2; - No suction equipment in three of three procedure rooms; and - No suction equipment in the pre/post procedure area. 7. During an interview on 03/12/19 at 9:25 AM in the pre/post procedure area, Staff O, Advanced Practice Registered Nurse (APRN), Clinical Manager, stated that: - There was no suction in the procedure rooms or pre/post procedure area. - She did not know where the suction machine	L1116		

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L1116	Continued From page 13 was located. - Staff needed an in-service on location of emergency equipment. 8. Observation on 03/12/19 at 9:30 AM in the pre/post procedure area showed: - An emergency box with emergency medications and supplies. * The emergency box did not contain suction supplies (suction tips or cannulas) or endotracheal equipment. During an interview upon the observation, Staff B, Registered Nurse (RN), stated that: - There was no suction supplies or endotracheal equipment in the pre/post area. - She did not know what emergency supplies were in the procedure rooms, she was only responsible for the pre/post procedure area. - She had worked at the facility for approximately three years. - She did not know where the suction machine was located. During an interview upon the observation, Staff O stated that she did not know where the endotracheal tubes were located. 9. During an interview on 03/12/19 at 10:05 AM, Staff EE, Physician, stated that: - If they had a patient that needed intubation he would use a LMA. - The LMA's were with the emergency supplies in the procedure rooms. - The facility had LMAs, oxygen, and suction for endotracheal equipment. - Given the facility's proximity to a hospital and EMS response time he had determined those supplies were sufficient for the facility.	L1116		

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L1116	Continued From page 14 10. During an interview on 03/12/19 at 10:10 AM, Staff H, Surgical Scrub Technician (staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), Patient Flow Coordinator, stated that: - The suction machine was in the sterile supply storage room. - They did not have suction tips or catheters for oral suction of the patient. - She did not know if the facility had laryngoscope handles and blades. - They did not have LMAs. 12. During an interview on 03/12/19 at 10:15 AM, Staff A, Director of Surgical Services, stated that she did not know where the suction tips or laryngoscope handles and blades were located or if they had them. 13. Observation on 03/12/19 at 10:20 AM of procedure room #3 and two sterile supplies closet showed there were no LMA or suction tips available for the facility. 14. Observation on 03/12/19 at 10:35 AM of sterile storage room #2 showed: - The laryngoscope handles and blades were stored together in a factory storage container on the top shelf. - The handles and blades had not been cleaned, high level disinfected, or packaged to prevent cross-contamination. (Note: The handles and blades were not ready for patient use.) During an interview upon the observation, Staff EE, stated that:	L1116		

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L1116	Continued From page 15 - The facility purchased laryngoscope handles and blades approximately one year ago. - They were stored on the top shelf in the supply room, still in the original case. - They would never use the laryngoscope handles and blades or the ET tubes. - He did not know the facility did not have any suction tips for oral suctioning. 15. During an interview on 03/13/19 at 11:00 AM, Staff N, Clinical Quality Implementation Manager, stated that: - The only checklist for staff to validate emergency supplies was the document, "Emergency Box," which was used for the pre/post procedure monitoring area. - The facility did not have an inclusive list of unit emergency supplies and equipment. - The monitoring tool for emergency supplies, "QM Monthly Site System Review Worksheet," did not include a list of emergency supplies and was not a tool to validate staff knowledge of emergency supplies. - The facility did not have a policy that outlined the required emergency supplies to be maintained by the unit; and - The facility did not have a policy that directed staff orientation and knowledge validation for the location and use of emergency supplies.	L1116		
L1131	19 CSR 30-30.060(4)(A) Infection control standards of the facility Infection control standards of the facility must be identified in writing, in compliance with generally-agreed upon national standards such as those of the Centers for Disease Control and Prevention (CDC), Association for Professionals in Infection Control and Epidemiology (APIC),	L1131		

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L1131	Continued From page 16 Association of peri-Operative Registered Nurses (AORN), or other standards determined acceptable by the department. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained a controlled environment to prevent cross-contamination in sterile processing and decontamination; - Staff followed acceptable sterilization standards and manufacturers instructions for use (IFU) for the monitoring of chemicals used for High-Level Disinfection (HLD) of instruments; - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for HLD of instruments; - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for steam sterilization; - Staff followed acceptable sterilization standards and facility policy for the labeling of sterile instruments and packages; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 216 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Managing Infection Prevention at Affiliates," dated 07/09/18, showed: - All staff is responsible for adhering to and incorporating infection prevention practices with	L1131		

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L1131	Continued From page 17 service provision. - The facility uses as a reference: * The Affiliate Risk Management Services infection Prevention Manual; * Centers for Disease Control and Prevention; * HealthCare Infection Control Practices Advisory Committee Guidelines; - Other resources are listed in the attachment section of this manual: * Association for the Advancement of Medical Instrumentation (AAMI); * Association of PeriOperative Registered Nurses (AORN); * Association of Professionals in Infection and Epidemiology (branch of medicine which deals with the incidence, distribution, and possible control of diseases and other factors relating to health); and * Occupational Safety and Health Administration. 2. Review of the AORN "Perioperative Standards and Recommended Practices for Instrument Cleaning," dated 2018, showed: - Recommendation V. * Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled. * Physical separation of decontamination areas (area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items) from areas where clean items are handled minimized the risk of cross-contamination. * Droplets and aerosols created during cleaning of soiled instruments can cause cross-contamination of any nearby clean items or surfaces. - Recommendation V.a.	L1131		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1131	Continued From page 18 * The sterile processing area should have: - Separate clean and decontamination spaces, which may be rooms or areas; - Decontamination and clean spaces that are separated by one of three methods: A wall with a door or pass-through, a partial wall or partition that is at least 4 feet high and at least the width of the counter, or a distance of 4 feet between the instrument washing sink and the area where the instruments are prepared for sterilization. - Recommendation VI. * Contaminated instruments are a potential source of transmissible pathogens. 3. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: 3.3.6.1.1 Design considerations: The decontamination area/room should be physically separate from all other processing areas and from areas in which clean or sterilization procedures are carried out, with any connecting doors and pass-through windows remaining closed. 4. Observation on 03/11/19 at 1:30 PM of the sterile processing area showed: - The pass through window between sterile processing and decontamination was open. - Staff F, Surgical Scrub Technician (ST, staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), was cleaning contaminated instruments in the decontamination room in direct proximity to the pass through window. - The door to the sterile processing room was	L1131		

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	MOA-0014	A. BUILDING: _____ B. WING _____	03/13/2019

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L1131	Continued From page 19 propped open. - Two sterilizers along the wall adjacent to the door that protruded past the door frame and prevented the door from being closed. During an interview upon the observation, Staff A, Director of Surgical Services, stated that the sterilizers blocked the door to sterile processing from closing. 5. Observation on 03/12/19 at 9:28 AM showed the doors to sterile processing and decontamination and the pass through window were open. 6. Observation on 03/12/19 at 11:25 AM showed the door to sterile processing and the pass through window was open. 7. During an interview on 03/13/19 at 9:15 AM, Staff A stated that the door to decontamination and the pass through window were to remain closed at all times. 8. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - E.6 Quality control in chemical disinfection (chemical substances which are used to kill or deactivate pathogenic microorganisms [capable of causing illness in humans]) * Dilution and minimum effective recommendation (MEC) / minimum recommended concentration (MRC) monitoring: The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in the	L1131		

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L1131	Continued From page 20 long-term use and reuse of a chemical disinfectant and can potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, excess moisture should be removed after cleaning. Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label. As part of a health care facility's quality control program, Liquid Chemical Sterilants (LCS)/HLD solutions such as glutaraldehyde (Cidex OPA [brand] - high level disinfectant for semi-critical medical devices) solution should be monitored upon activation and before each use in order to detect unexpected dilution of the solution. 9. Review of the AORN "Guideline for Manual Chemical High-Level Disinfection," dated 2018, showed: - Recommendation IV.d. * High-level disinfection should occur in a designated clean area that is separate from the decontamination area. * Separating the clean area from the area where devices are cleaned and prepared for high-level disinfection reduces the risk of device contamination that might occur when both clean and contaminated processing activities are performed in a single area. - Recommendation VI.c.1. * A test strip or other Food and Drug Administration-cleared testing device specific to the disinfectant and the active ingredient in the disinfectant should be used before each use of the HLD solution. - Recommendation VI.d.1.	L1131		

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L1131	Continued From page 21 * The temperature of the HLD solution should be verified before each use with a thermometer calibrated within the applicable range. - Recommendation IX: * Documentation should be completed to enable the identification of trends and demonstrate compliance with regulatory and accrediting agency requirements. - Recommendation IX.a. * Records related to manual chemical high-level disinfection should include: The date and time of high-level disinfection; HLD solution lot number; HLD solution shelf-life date; HLD solution activation date; HLD solution reuse-life date; Results of solution test strip testing; Results of MRC or MEC testing, if applicable; HLD solution temperature; HLD solution exposure time; Quantity and description of the device or item; and Identity of the person performing high-level disinfection. 10. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18, showed to ensure integrity, visually inspect previously used solution before use, test and record results in appropriate testing log daily. 11. Review of the manufacturer's IFU for Cidex OPA showed: - Reuse for Disinfection: * The concentration of Cidex OPA Solution during its use-life (time between activation of the solution and last date to be used) must be verified by the test strips prior to each use. * This is to ensure the minimum effective	L1131		

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L1131	Continued From page 22	L1131		

concentration is present.
* Cidex OPA Solution may be used for up to a maximum of 14 days provided the required conditions of concentration and temperature exist.

12. Review of the facility's documents titled, "Cidex OPA Solution MEC test log showed:
- The document was used to record the following information:
* Date the solution was poured into the secondary container (a soaking pan);
* Staff initials;
* MEC test strip results; and
* Comments/resolution.
- Review of the monthly logs showed:
* 11/18 - entries on three days;
* 12/18 - entries on three days;
* 01/19 - entries on four days;
* 02/19 - entries on seven days; and
* 03/01/19 - 03/11/19 - entries on four days:
* Staff documented that the solution was changed four times in 19 weeks.
- Staff failed to document:
* The date and time of high-level disinfection;
* HLD solution lot number;
* HLD solution reuse-life date;
* HLD solution exposure time; and
* Quantity and description of the devices or items disinfected.

13. During an interview on 03/13/19 at 8:35 AM, Staff F stated that:
- Staff checked the Cidex daily;
- They only checked the Cidex on days they had procedures that required HLD.
- The Cidex expired 14 days after it was mixed regardless of the MEC.
- The number of HLD loads disinfected averaged

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L1131	Continued From page 23 between 12 and 15 HLD loads per day on procedure days. - She did not check the Cidex MEC prior to disinfection of each load. 14. During an interview on 03/13/19 at 9:30 AM, Staff A stated that: - She did not know the Cidex MEC should be validated prior to each HLD load of instruments; and - She was not aware the time of high-level disinfection, solution lot number, reuse-life date, exposure time, quantity, and description of the device or item disinfected should be documented. 15. Review of the ANSI/ AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2018, showed: - 13.3.3 Sterilizer records * The process critical parameters (time and temperature) provided on the recording chart, printer, or tape should be reviewed, signed, and dated by the operator to indicate an acceptable cycle. * For each sterilization cycle, the following information should be recorded: (a) The load number; (b) The specific contents of the lot or load, including quantity, department, and a specific description of the items(e.g., towel packs, type/name of instrument sets); (c) The exposure time and temperature, if not provided on the sterilizer recording chart; and (d) Operator identification. 16. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18,	L1131		

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L1131	Continued From page 24 showed: - Information that should be recorded and maintained for each sterilization cycle includes guidance from Consolidated Test of American National Standard/Advancing Safety in Medical Technology: * Specific contents of the lot or load, including quantity, department, and specific description of the items (e.g. towels, type/name of instrument sets); * Exposure time and temperature, if not provided on the sterilizer recording chart; * Name or initials of operator; and * Results of biological testing, if applicable. 17. During an interview on 03/12/19 at 9:15 AM in the sterile processing room, Staff D, ST, stated that: - They did not maintain a sterilization log. - She never had any training on the sterilization process; she just continued to do what she had seen was done in the past. - She only logged sterilizer cleaning and results of the biologicals. - Each instrument package and set should be labeled with a load number and autoclave number. - She did not know they should keep a record of the content, time and temperature for each sterilizer load. 18. During an interview on 03/12/19 at 9:30 AM in the sterile processing room, Staff A stated that: - They tested the Cidex OPA solution daily. - She did not know they were supposed to test the Cidex OPA solution before every load of instruments processed. - They did not have a log to document load content, time, and temperature for the Cidex OPA	L1131		

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L1131	Continued From page 25 solution or the steam sterilizers. 19. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - 13.3.1 General considerations * Each item or package intended for use as a sterile product should be labeled with a lot control identifier to allow full traceability of that item to the patient. * Each load should have a load control record that includes a detailed content list, including specific identification of sets and the contents of sealable pouches. - 13.3.2 Package labeling * Each item or package intended for use as a sterile product should be labeled with a lot control identifier prior to sterilization. The lot control identifier should identify: a) The sterilizer identification number or code; b) A detailed list of the contents (e.g., identification of multiple sets and the contents of paper-plastic pouches); c) The person who assembled the package; d) The date of sterilization; e) The cycle number (cycle run of the sterilizer); and f) The patient, if applicable. - Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for proper stock rotation. Lot identification enables personnel to retrieve items in the event of a recall and to trace problems (e.g., wet packs) to the source. Pre-sterilization labeling can be done after sterilizer and cycle assignment is determined and as the cart is loaded. Accountability to the patient and surgeon for the	L1131		

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L1131	Continued From page 26 sterility of a reprocessed device requires documentation that can be traced to the patient. Traceability is especially important as the consequences of infection can result in increased morbidity and mortality. 20. Review of the facility's policy titled, "Cleaning, Disinfection and Sterilization," dated 07/09/18, showed: - Documentation establishes accountability by documenting what instruments have been processed and provides evidence of monitoring controls for those items. * In the event of a sterilization process failure, good records will help the staff trace each package back to the event itself. * Each item or pack should be labeled with a lot identifier that designates the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). *Lot identification enables retrieval of items in the event of a recall, tracing problems to their source and facilitates proper stock rotation. 21. Observation on 03/11/19 at 3:00 PM in the sterile processing room showed 13 of 26 sterile instrument packages observed did not have a sterilizer or load number identified on the package. During an interview upon the observation, Staff O, Clinical Manager, stated that she did not know the sterilizer and load number should have been identified on the packages of sterilized instruments. Staff F stated that she did not know she was supposed to label every instrument package with the sterilizer number and load number.	L1131		

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L1131	Continued From page 27 22. Observation on 03/11/19 at 1:30 PM in the sterile supply storage room showed: - A box of 50 infusion sets (small tubing with needle inserted into a vein for administering medication and fluid) that had expired 08/18. - Staff A removed the box of expired supplies. During an interview upon the observation, Staff A stated that Staff H, Patient Flow Coordinator and Staff T, Shipping and Receiving Coordinator, were responsible for checking for expired supplies at least monthly. 23. Observation on 03/11/19 from 1:50 PM through 2:45 PM during tour of the patient care areas, showed seven expired cans of alcohol-based hand sanitizer with expiration dates ranging from 08/18 through 12/18. 24. During an interview on 03/13/19 at 11:02 AM, Staff O stated that she did not know who was responsible to monitor the expiration dates of the alcohol-based hand sanitizer. 25. During an interview on 03/13/19 at 11:10 AM, Staff H stated that she did not know who was responsible to monitor the expiration dates of the alcohol-based hand sanitizer.	L1131		
L1146	19 CSR 30-30.060(5)(F) The facility shall follow all applicable laws The facility shall follow all applicable laws and regulations pertaining to controlled substances. This regulation is not met as evidenced by: Based on state statute, policy review, record review, and interview, the facility failed to:	L1146		

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L1146	Continued From page 28 - Ensure controlled substance logs were maintained to include the addresses of patients who received controlled substances; and - Ensure controlled substance logs were maintained to include the reason for the destruction or wastage of controlled substances not administered. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 cases. Findings included: 1. Review of Missouri's 19 Code of State Regulations (CSR) 30-1.048(1)(3), dated 04/30/17, showed: - Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed: * The name of the substance; * Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial); * The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received; * The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume	L1146		

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L1146	Continued From page 29	L1146		

dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance; and
* The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.
- Individual practitioners shall maintain the records listed in subsections (1)(A)-(E) of this rule separately from patient medical records.

2. Review of Missouri's 19 CSR 30-1.078(5) showed the following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry.

3. Review of the facility's policy titled, "Policy Statement & Work Practices for Management of Controlled Substances," dated 04/30/18, showed:
- The dispensing log must include the date dispensed, patient name, patient address, drug name, strength, dosage form and quantity dispensed, and the name/initials of the person performing the dispensing.
- The chief circumstances for disposal of unwanted controlled substances are:
* The drug has been contaminated by patient contact, left over injectable drugs in a syringe, or a tablet that has fallen out of a patient's hand or mouth. In these cases the drug may be

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L1146	Continued From page 30 destroyed by two employees. The drug must be destroyed beyond reclamation and documented as described below. * When practitioners administer injectable controlled substances, there will be a small amount remaining in the hub of the syringe. These are considered insignificant in the course of normal practice. These amounts are not considered lost. They should be documented on the logs so they are accounted for and records balance. (Note: The facility did not include documenting the reason for wastage in their list of required documentation.) 4. Review of the facility's documents titled, "Controlled Substance Dispensing Or Administration Log," dated 01/30/19 through 03/13/19, showed: - Staff did not include the patients' addresses on the log; and - Staff did not document the reason controlled substances were wasted. 5. During an interview on 03/12/19 at 9:00 AM, Staff B, Registered Nurse, stated that: - They did not document the patient's address on the "Controlled Substance Dispensing Or Administration Log;" and - Staff did not document the reason controlled substances were wasted unless the reason for wastage was something "weird."	L1146		

Missouri Department of Health and Senior Services

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/11/19 to 03/13/19 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Reproductive Health Services of Planned Parenthood	Survey Exit Date	3/13/19
Facility Address/ City/Zip	4251 Forest Park Avenue, St. Louis, MO 63108	Statement of Deficiencies (SOD): L-tags	L069, L1069, L1076, L1103, L1116, L1131, L1146

1. **Include a <u>copy of the first page of the original Statement(s) of Deficiencies</u>** for the State (L-tags) **<u>signed & dated by administrator</u>** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **<u>Required elements of an acceptable Plan of Correction</u>**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc.).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. <u>EVIDENCE/EXHIBIT ATTACHMENTS(s).</u> If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

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MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
L069	In accordance with 19 CSR 30-30.020(1)(A)(6) Reproductive Health Services shall hold an additional Fire Drill to be documented separately from the Central West End Health Center and Administrative Offices to prevent future confusion regarding the staff list on the drill and the separate sign in sheet with Reproductive Health Center Staff signatures. The fire drill evacuation continues to be an annual requirement. Reproductive Health Services shall perform an additional fire drill to ensure all staff has an opportunity to participate and familiarize themselves with their assigned emergency duties. If any staff were not present on the day of the fire drill then a separate fire drill will be held to ensure that all staff have participated. The fire drill shall be performed no later than April 30, 2019 to ensure staff who missed the November fire drill have participated. Patient Services Orientation shall continue to include onboarding of the	4/30/19	Clinical Quality Improvement Manager & Compliance Administrator	The facility fire drills shall continue to be an annual obligation of the Compliance Quality and Risk Management system. RHS shall have a separate fire drill and signature sheet from the Administrative Office to prevent misunderstanding of the number of participants. Staff participation shall be audited until compliance has been achieved to satisfy the requirements of the State Inspection. The audit shall be incorporated in the Quality Assessment and Performance Improvement (QAPI) program until compliance is achieved.	N/A

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A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	emergency procedure to familiarize staff with the fire drill policy and evacuation plan.				
L1069 (#1-2) L1103 (#1-7)	The facility has ensured that the written policy is updated to reflect current practices which comply with all regulatory requirements for obtaining a complete medical history and pelvic examination. The facilities' Medical Standards and Guidelines (MS&Gs), Abortion: Chapter 1, pages 10 and 29 includes specific language indicating that pelvic examinations are performed prior to all abortions, whether medication or surgical. Language stating that a comprehensive medical history must be completed prior to any medication or surgical abortion is included as well. Pregnancy shall be confirmed for any abortion patient by both ultrasound examination and urine hCG testing as required by Missouri regulations. Per the Missouri Department of Health and Senior Services, Statement of Deficiencies and Plan of Correction, Survey dated 03/07/2018, State Form, page 25 of 28, ID Prefix Tag L1163 which specifically states that an ultrasound is "a machine that utilizes high-frequency sound waves to produce images of structures within the body", thereby	Clinical Manager	04/30/2019	Affiliate Medical Standards and Guidelines shall be updated as described in the plan of correction action Column B. This information shall include all components as described; an attachment of the updated MS&Gs Abortion Chapter 1 pages 10 and 29 is included for review. The Clinical Manager shall ensure that the policies are updated and that documentation continues to occur as required by state regulations and the facilities' updated standards and guidelines. The Clinical Manager will review the updated policies in the Quality Assessment and Performance Improvement (QAPI) program.	MS&Gs Chapter 1, page 10 & 29

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	indicating that the utilization of an ultrasound for determination of pregnancy, which is performed on every abortion patient, has the capacity to specifically identify the structure of the uterus, which aids the providing physician the ability to determine the direction and shape of the uterus, and such information can be utilized, in conjunction with the complete medical history and other state-required labs, to decide upon and determine the best procedure, as well as preoperative and postoperative management for each individual patient. Therefore, information from the complete history, health assessment, and required ultrasound shall be utilized to appropriately determine gestation, identify preexisting medical or other complications, and detecting factors which could influence procedure type, anesthesia, or preoperative and postoperative management. Because the health assessment, including a pelvic examination, is completed prior to the procedure, findings from the assessment would influence the choice of the planned procedure and pre-operative management. All required exams and findings, including the pelvic examination, are documented in the patient's medical				

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ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	record. The documentation includes the date on which the examination is performed. Thus, contrary to Findings #3–5, Tag L1103, the date of the pelvic exam was documented in the medical records of patients #1, #2, #3, #4, #5, #6, #7, #8, #10. Missouri regulations provide that "[a] health assessment including a pelvic examination shall be performed." RHS complies with this requirement by performing a pelvic examination for every surgical and medication abortion patient prior to the procedure. Review of statements from the Missouri Department of Health and Senior Services, Statement of Deficiencies and Plan of Correction, Survey dated 03/07/2018, State Form, page 21 of 28, ID Prefix Tag L1163 specifically states the pelvic examination requirement shall be satisfied as follows: "Ensure a pelvic examination (visual and physical examination of a woman's reproductive organs [the vagina, cervix, fallopian tubes, vulva, ovaries, and uterus] for any abnormalities) was completed prior to the procedure". The statement also provided: "Ensure a physical examination was completed immediately prior to the procedure, in order to evaluate the procedural risks" of the procedure for the				

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ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	patient. The facility's policies are in accord with the regulation, as understood by the Missouri Department of Health and Senior Services. Furthermore, state inspectors observed our physician (Staff EE, MD) perform the pelvic exam prior to the start of a surgical abortion procedure, which is what the regulation requires. Pursuant to Missouri regulation 19 CSR 30-30.060(1)(A)(1), the current facilities' Medical Standards and Guidelines satisfy this regulation as they specifically and purposefully state, per regulations, that all components necessary to be completed are done so in accordance with the law.				
L1076 (#1-6)	The facility rigorously strives to abide by all applicable state and federal laws and regulations, including Chapter 188, RSMo. Under Chapter 188.027 RSMo., "[t]he physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of" the information required in the statute. The facility complies with this requirement in all cases, including in the case of patient #7 and #10. As the Missouri Department of Health and Senior	04/30/2019	Clinical Manager	Attending physician staff shall be educated on the importance of proper documentation and specifically the necessity of signing off as the supervisor for all medical charts. Furthermore, a representative sample of charts shall be audited to ensure adherence to this education until compliance is achieved. The audit shall be incorporated in the Quality Assessment and Performance Improvement (QAPI) program until compliance is achieved.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	Services told the Circuit Court of Jackson County in its legal filings: "When there are two or more physicians who are substantially involved in performing or inducing the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109. In the case of medical record #10 the Missouri Department of Health and Senior Services deficiency states that mifepristone was given by a Fellow Physician who was practicing under the supervision of an Attending Physician, and not by the Attending Physician who provided the information required by 188.027.6 RSMo. seventy-two hours prior, which is not correct. The Attending Physician provided the medications to patient #10 and signed the Mifeprex agreement attesting to that fact. The Mifeprex agreement, which is in the patient medical record demonstrates this fact				

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ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	and states: "Mifepristone administered to patient in clinic at xx:xx PM [identifying time redacted] under observation by the Attending Physician, DO [name redacted]". In regards to the case of patient #7, the facility complied with Chapter 188.021.6 RSMo. because the Fellow Physician, who handed the medications to the patient, was practicing under the supervision of the Attending Physician and who was physically present and participated in and supervised the care of the patient. The original documentation from the day of the procedure supports that the Attending Physician was substantially involved in the patient's care. The Attending Physician on that day physically signed the "Physicians Orders and Medication Administration Record" with the box for mifepristone selected, which was scanned into the medical record. Within the final Visit Summary for the day of the procedure resides proof that the medication was administered as documented under the "Medications Prescribed for this Visit" tab.				

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	The list of medications prescribed include "Mifeprex 200mg PO administered to pt in clinic, 1 ordered, ordered by Attending Physician, MD [name redacted], transaction category: administered." In addition, Finding #6 observes that the Attending Physician "was in the room" during the procedure. The Attending Physician made an error in documentation by neglecting to sign off the medical record as the supervising provider. However, the Attending Physician did make an addendum at a later date, which states, in part, the following: "I supervised Fellow Physician [name redacted], throughout this clinical encounter, including with the provision of mifepristone for medication abortion as is reflected by my signature on medication documentation from that encounter." The facility will ensure that the Attending Physician will complete a supervisory note in all patient records for whom the Fellow Physician hands the patient the medications, including re-educating the Attending Physician of this requirement. Therefore, the facility is in				

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	compliance with current regulations, and the errors in documentation have been appropriately addressed including re-education of the attending physicians signing off as the supervisor for all medical charts.				
L1116	Reproductive Health Services, in accordance with 19 CSR 30-30.060(2)(N) has emergency drugs, oxygen, and intravenous fluids in the procedure room to stabilize the patient's' condition when necessary. Additionally, manual breathing bag, suction machine and endotracheal equipment shall be located in the clinical area for immediate access by April 30, 2019. The portable suction machine noted in the Reviewers' Summary as located in the storage area will be moved to post procedure area, known as Recovery Room by April 30, 2019 The emergency equipment located in the post procedure area known as the recovery room. The following emergency equipment is kept in the recovery area: • Endotracheal equipment: laryngeal mask airway (LMA), & Ambu bag • Suction machine and necessary	4/30/19	Director of Surgical Services & Clinical Quality Improvement Manager	The updated Emergency Inventory checklists shall continue to be completed weekly. While there was reference to there are no references to AORN within the Missouri regulation 19 CSR 30.30.060 Ongoing Patient Services Staff Orientation to reiterate Patient Services Orientation Checklist under section Medical Emergencies #5 Location & Use of Emergencies Equipment/Supplies during orientation onboarding. Staff shall be retrained on location and operation of emergency equipment. Staff shall be provided an education & training on the emergency box with the emergency medication and supplies location and operations by end of April 2019. The training shall be reviewed in the Quality Assessment and Performance Improvement (QAPI)	Emergency Inventory checklists for procedure rooms and recovery room attached MS&G Chapter 1. Abortions 1.3 Management of Abortion Complications p. 38. Emergency Care Manual, Emergency Medications and Supplies

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	equipment to utilize the machine, including tubing and Yankauer suction tips. Edit the Emergency Inventory procedure rooms and recovery room checklists to include suction tubing and Yankauer. The Yankauer and suction tubing was ordered on 4/5/19. In accordance with 19 CSR 30-30.060(2)(N) Reproductive Health Services shall maintain endotracheal equipment in addition to our Ambu bag noted in the regulations as the manual breathing bag, and a suction machine in a readily available location in the clinical area. LMA equipment was ordered as part of our resuscitation and emergency medical supplies. The emergency medical equipment laryngoscope has been removed from the facility area, as it will not be used as resuscitative equipment at Reproductive Health Services. The Emergency Inventory checklists kept in each procedure room and the Recovery room currently contain the list of specific emergency medical supplies. The Emergency Inventory Log, Any overstock of			program. "Emergency Inventory Log" attached for authentication of weekly review of emergency and resuscitative equipment in procedure rooms. Recovery room emergency equipment checklist "Emergency Inventory Recovery Room" edited to include Yankauers, Suction Machine, LMA and suction tubes. Continued monthly documentation of QM Site System Review by Director of Surgical Services or designee. Edit Nurse Supervisor for Emergency Equipment to Designee. Edit Emergency Equipment to include resuscitation equipment, and Verify Emergency Inventory Checklist for each Procedure Room & Recovery completed. The Emergency Inventory Checklists include emergency equipment list.	p. 14 Emergency Medications & Supplies List attached

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	Yankauer or suction tubing to be kept in the supply room. Finding #3 confuses the difference of an Emergency Transfer and an Emergency. Medical Standards & Guidelines 1.3 Management of Abortion Complications on page 38 states prior to policy 1.4.c Emergency Response Protocol and Procedure for Emergency Transfer of Patients in Life Threatening Situation, "Refer to ARMS Emergency Manual for management of acute emergencies." Reference to the Emergency Care Manual is currently in the Medical Standards and Guidelines related to emergencies in section 1.3 Management of Abortion Complications. The section referenced in L1116 is specific only to emergency transfers. The Emergency Care Manual contains the emergency equipment necessary to treat seizures, bleedings, anaphylactic shock, respiratory arrest, and cardiac arrest and other life threatening emergencies on the Emergency Medications and Supplies listed on page 14. Staff training will reiterate emergency equipment function and location of equipment.				

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	The Emergency Care Manual's Reproductive Health Services Emergency Medications and Supplies has been updated and included as proof of inclusive list of unit emergency supplies and equipment. Staff will be trained and educated on the emergency box with emergency medications and supplies. Emergency and resuscitative equipment checklist located on a weekly Review titled "Quality Management (QM) Site System Review" to more clearly show that the emergency equipment is listed on the Emergency Inventory Checklist. Laryngoscope has been removed from the facility of Reproductive Health Services area. Training of designated staff to reiterate initialing space provided for Emergency Equipment on the "Emergency Inventory forms" The portable suction machine shall be moved to the Recovery Room location, with the suction tubes, laryngeal mask airway,				

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	and the Yankauer. Each procedure room will be stocked with suction tubing, Yankauer suction tip. In addition, staff in-service training on the equipment location and operation to be completed in April 2019.				
L1131	Reproductive Health Services Infection Control standards, in accordance with 19 CSR 30-30.060(4)(A) shall maintain a controlled environment and follow all manufacturer's instructions and guidelines concerning High-Level Disinfection (HLD). HLD Log edited to include: - Date and time of HLD disinfection - HLD solution lot number - HLD solution shelf-life date - HLD solution activation date - HLD solution reuse-life date - Results of solution test strip testing - HLD solution temperature	4/30/2019	Director of Surgical Services	Staff shall be educated by April 30, 2019 on the edits to the High-Level Disinfection Log. The Director of Surgical Services shall audit for compliance to the updated standards by checking the logs weekly for adherence. Reproductive Health Services has updated the Quality Management Site System review to include the audit of wall hand sanitizer to ensure none are expired. Staff educated on marking the new canisters appropriately. Furthermore, wall hand sanitizers are included in the monthly log for review as items to be checked to ensure compliance with not being	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	- HLD solution exposure time - Quantity and description of the device or item - Identity of the person performing high-level disinfection. All Reproductive Health Services staff will be trained to document the required monitoring controls for HLD regarding the disinfection of instruments as directed in the manufacturer's instructions. . Each log shall include each disinfection use including the item(s) sterilized and the quantity. Temperature of the HLD solution shall be verified with a thermometer calibrated within the applicable range according to the manufacturer's instructions. Labeling of sterile instruments and packages. Log edited to include: -The sterilizer identification number (machine 1 or machine 2) -A detailed list of contents (i.e. 2 LAM Packs, 4 two pack dilators) -The person who assembled the package -The date of sterilization -The cycle number All staff shall be trained to follow the acceptable sterilization standards and facility			expired. Staff shall be trained to keep the proper window and doors closed in the decontamination area in order to prevent cross-contamination and to adhere to best practices. Director of Surgical Services shall review with the Quality Assessment and Performance Improvement (QAPI) program Infection Control standards in accordance with 19 CSR 30-30.060(4)(A) changes until compliance is achieved.	

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	policy for labeling of sterile instruments and packages. Expired wall hand sanitizers were removed and disposed of. New and non-expired hand sanitizers were placed in the wall holders, and the date of expiration was marked on the side of the canister in bold lettering. Reproductive Health Services currently has a physical separation of decontamination area from areas where clean items are handled to minimize the risk of cross-contamination. A smaller autoclave has been ordered to reorganize the sterilization room to be able to close the door properly. The current pass-through window shall remain closed except when passing clean/disinfected equipment from the decontamination area to the sterilization room. Both doors to the decontamination room and the sterilization room shall remain closed at all times				
L1146	Reproductive Health Services shall follow all applicable laws pertaining to controlled substances pursuant to 19 CSR 30-1.048(1)(3). The controlled substance logs shall be updated to include the addresses of patients who received controlled substances.	4/30/19	Clinical Manager, Quality Manager	Regular audits shall be performed of the updated controlled substance logs in order to ensure compliance to best practice standards and documentation by adding it to the monthly QM System Site Review checklist. The audit shall be incorporated in the Quality	Attachment Controlled Substance Administration & Disposal Log

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	*Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.*	*Correction Date*	*Title of Person Responsible for Correction. No names*	*Describe monitoring procedure to ensure continued compliance, to include:* - *Frequency/duration of monitoring* - *Method of data collection* - *Who monitors, if different than "**D**"*	*Evidence/ Exhibit Attachment Numbers or "N/A"*
	The controlled substance logs, in accordance with subsection list (1)(A)-(E), shall be recorded separately from patient medical records. Reproductive Health Services, has updated the Missouri Department of Health & Senior Services Bureau of Narcotics and Dangerous Drugs Controlled Substance Dispensing or Administration Log to be in compliance with 19 CSR 30-1.048 & 19 CSR 30-1.78(5) including reason for wastage. Staff shall be trained on the updated log, including documenting the reason for wastage. Staff shall be trained in the practice of including patient addresses on the edited Controlled Substance Administration and Disposal Log			Assessment and Performance Improvement (QAPI) program until compliance is achieved.	

Condition	B	C
Patient factors		
▪ Unwilling to have an aspiration abortion	●	
▪ Cannot follow up to confirm the pregnancy was terminated	●	
▪ Does not have access to a telephone, emergency medical care (emergency treatment of incomplete abortion, blood transfusion or emergency resuscitation), and transportation	●	
Porphyria – inherited	●	
Renal failure	●	
Respiratory disease – chronic		●

1.1.3 Medical Screening and Evaluation

1.1.c. Table: Medical Screening and Evaluation – Medication Abortion

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ LMP ▪ Comprehensive medical history ▪ Screening to identify possible contraindications and/or special conditions	**Must** include ▪ BP ▪ Bimanual exam when indicated (e.g., vaginal bleeding or abdominal/pelvic pain, or as required by Missouri regulations) ▪ Additional examination as indicated by history or laboratory findings	**Must** include ▪ Hgb or hct ▪ Rh typing — unless patient reports Rh-negative status or written documentation of Rh status is available. ▪ GC/CT Testing per CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines ▪ Ultrasound confirmation of gestational age* ▪ Other tests as indicated

* *PER Missouri 1 CSR 30-30 E, Ultrasounds at abortion facility to confirm gestational age and for other imaging purposes such as ultrasounds per 188.027(4) shall be performed by a physician or person who holds a current certification by the American Registry for Diagnostic Medical Sonography (ARDMS).*

1.1.14 Medical Screening and Evaluation

1.2.c. Table: Medical Screening and Evaluation – Surgical Abortion

History	Physical Examination	Laboratory Testing and Diagnostic Imaging
Must include ▪ LMP ▪ Comprehensive medical history ▪ Screening to identify possible contraindications and/or special conditions ▪ Allergies to medications, antiseptic solutions, and latex For digoxin use ▪ Assessment of family history for sudden cardiac death in young healthy family member or strong family history of cardiac arrhythmias	**Must** include ▪ Temperature, if symptomatic of infection ▪ BP ▪ Visual exam of the vulva, vagina, and cervix ▪ Bimanual exam, including estimation of uterine size and position and palpation of the adnexa ▪ Abdominal palpation (not required when ultrasound and bimanual exam are consistent with gestational age) ▪ Additional examination as indicated by history or laboratory findings For digoxin use ▪ Cardiac auscultation	**Must** include ▪ Urine or blood pregnancy test performed at affiliate within 7 days, unless ultrasound documented an intrauterine pregnancy ▪ Hgb or Hct ▪ Rh typing — unless patient reports Rh-negative status or written documentation of Rh status is available. ▪ GC/CT testing per CDC STD Treatment Guidelines ✓ CDC STD Treatment Guidelines ▪ Ultrasound, if indicated* ▪ Other tests as indicated ✓ FYI - Bacterial Vaginosis and Abortion

* *PER Missouri 1 CSR 30-30 E, Ultrasounds at abortion facility to confirm gestational age and for other imaging purposes such as ultrasounds per 188.027(4) shall be performed by a physician or person who holds a current certification by the American Registry for Diagnostic Medical Sonography (ARDMS).*

Reproductive Health Services of Planned Parenthood of the St. Louis Region
4251 Forest Park Avenue, 63108 314-531-7526

QM Monthly Site System Review **Month_____/_____**

To be completed monthly by Director of Surgical Services/Delegate

Site_____ **Auditor**_____

<table>
<tr><th>Date</th><th>System Reviewed
(During Clinical Operations Including Patient Care/Interactions)</th><th>Guidelines Met</th><th>Guidelines Not Met</th></tr>
<tr><td></td><td>Exit and pathways in the surgical center are clear</td><td></td><td></td></tr>
<tr><td></td><td>Ceiling vents clear of dust and debris</td><td></td><td></td></tr>
<tr><td></td><td>Computer passwords are secured and not visible</td><td></td><td></td></tr>
<tr><td></td><td>Universal Precautions used by all staff (Including before & after pt contact)

<table>
<tr><td>{Initials of staff observed}</td><td>Compliant</td><td>Non-Compliant</td></tr>
<tr><td>Lab staff { } { }</td><td></td><td></td></tr>
<tr><td>Sono staff { } { }</td><td></td><td></td></tr>
<tr><td>Procedure Room staff { } { }</td><td></td><td></td></tr>
<tr><td>Decontamination staff { } { }</td><td></td><td></td></tr>
<tr><td>Sterilization staff { } { }</td><td></td><td></td></tr>
<tr><td>Environmental Services staff { } { }</td><td></td><td></td></tr>
</table></td><td></td><td></td></tr>
<tr><td></td><td>Personal Protective Equipment available & appropriately used (i.e. masks, lab coats, gloves in various sizes, face shield, vinyl gloves, utility gloves) as appropriate for job duty

<table>
<tr><td>{Initials of staff observed}</td><td>Compliant</td><td>Non-Compliant</td></tr>
<tr><td>Lab staff { } { }</td><td></td><td></td></tr>
<tr><td>Sono staff { } { }</td><td></td><td></td></tr>
<tr><td>Procedure Room staff { } { }</td><td></td><td></td></tr>
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<tr><td>Sterilization staff { } { }</td><td></td><td></td></tr>
<tr><td>Environmental Services staff { } { }</td><td></td><td></td></tr>
</table></td><td></td><td></td></tr>
<tr><td></td><td>Steps to follow when an accident occurs involving workers compensation is posted and forms readily available for staff</td><td></td><td></td></tr>
<tr><td></td><td>Emergency equipment audited by designee (_____) (initials)
Resuscitative equipment First Aid Kit Spill Kit/Supplies
Flashlights and back up lighting operable Ammonia Capsules Defibrillator
Exit lighting operable
Verify Emergency Inventory Checklist for each Procedure Rm & Recovery completed</td><td></td><td></td></tr>
<tr><td></td><td>Fire Extinguishers easily accessible, charged, inspection current for monthly and annually</td><td></td><td></td></tr>
<tr><td></td><td>MSDS Log current with supplies that are used in the health center: randomly checked the following area & supplies for MSDS sheets
<table>
<tr><th>Area</th><th>Supply Name</th><th>MSDS—yes/no</th></tr>
<tr><td>Lab</td><td></td><td></td></tr>
<tr><td>Sono</td><td></td><td></td></tr>
<tr><td>Procedure</td><td></td><td></td></tr>
<tr><td>Decon/Steriliz</td><td></td><td></td></tr>
<tr><td>Enviro Services</td><td></td><td></td></tr>
</table></td><td></td><td></td></tr>
</table>

Americans United for Life

<table>
<tr><th>Date</th><th>System Reviewed
(During Clinical Operations Including Patient Care/Interactions)</th><th>Guidelines Met</th><th>Guidelines Not Met</th></tr>
<tr><td></td><td>Environmental Care: Rooms & Equipment Clean, free from dust & debris
-Overall cleanliness of area (floors, counters, shelving, drawers, cabinets)
-Smooth cleanable surfaces
-Regular and biohazard trash not over flowing containers
-Disinfectant solution available
-Surface decontamination performed per infection control protocol
-Equipment clean
-Carts clean
-Segregation of clean/sterile items
-Shelving for sterile instruments clean and dry with protective barrier on bottom shelf
-Functional work areas physically separated by wall/closed sliding door during instrument reprocessing area (in decontamination area)
-Corrugated boxes not in clinical care/storage areas
<table><tr><th></th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab Area</td><td></td><td></td></tr><tr><td>Sono rooms</td><td></td><td></td></tr><tr><td>Procedure rooms</td><td></td><td></td></tr><tr><td>Recovery room</td><td></td><td></td></tr><tr><td>Decontamination room</td><td></td><td></td></tr><tr><td>Sterilization room</td><td></td><td></td></tr><tr><td>Storage rooms</td><td></td><td></td></tr><tr><td>Work stations</td><td></td><td></td></tr><tr><td>Education/Interview rooms</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Staff use protective equipment for patient interactions, cleaning of rooms and equipment management as necessary</td><td></td><td></td></tr>
<tr><td></td><td>All specimens labeled, handled appropriately and staff follows general packaging requirements</td><td></td><td></td></tr>
<tr><td></td><td>Disposed specimen containers with PHI de-identified before disposal</td><td></td><td></td></tr>
<tr><td></td><td>Single use suction tubing discarded after each procedure</td><td></td><td></td></tr>
<tr><td></td><td>Decontamination receiving and clean/sterilized items separated</td><td></td><td></td></tr>
<tr><td></td><td>Checklist completed by assigned staff
-Daily lab refrig temp & cleaning documented -Decontamination & Sterilization Procedures documented -Sterilizer indicator with each autoclave batch -Weekly & Monthly autoclave cleaning -Daily Spore Testing with each load documented for each autoclave machine-Weekly air jet & Monthly safety valve check</td><td></td><td></td></tr>
<tr><td></td><td>Inventory & Control Logs current and completed</td><td></td><td></td></tr>
<tr><td></td><td>No expired medication/supplies/merchandise on shelves or in clinical area
<table><tr><th></th><th>Compliant</th><th>Non-Compliant</th></tr><tr><td>Lab</td><td></td><td></td></tr><tr><td>Sono rooms</td><td></td><td></td></tr><tr><td>Procedure rooms</td><td></td><td></td></tr><tr><td>Recovery room</td><td></td><td></td></tr><tr><td>Decontamination room</td><td></td><td></td></tr><tr><td>Sterilization room</td><td></td><td></td></tr><tr><td>Storage areas</td><td></td><td></td></tr><tr><td>Wall hung hand sanitizer</td><td></td><td></td></tr></table></td><td></td><td></td></tr>
<tr><td></td><td>Multi-dose vials dated when opened: documentation of date/time opened & staff initials & discarded within 28 days</td><td></td><td></td></tr>
<tr><td></td><td>Multi-dose vials restricted to centralized area of designated nurses station
-Prepared medication syringes in drawer labeled “injectable” medicine at Nurses’ Medication Prep Station in recovery area</td><td></td><td></td></tr>
<tr><td></td><td>Controlled substance log has appropriate documentation completed when applicable</td><td></td><td></td></tr>
</table>

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<table>
<tr><th>Date</th><th>System Reviewed</th><th>Guidelines Met</th><th>Guidelines Not Met</th></tr>
<tr><td></td><td>Sharp Collectors placed on shelves or in wall brackets
<table>
<tr><td></td><td>Compliant</td><td>Non-Compliant</td></tr>
<tr><td>Lab area</td><td></td><td></td></tr>
<tr><td>Sono room</td><td></td><td></td></tr>
<tr><td>Procedure room</td><td></td><td></td></tr>
<tr><td>Recovery room</td><td></td><td></td></tr>
<tr><td>Decontamination room</td><td></td><td></td></tr>
<tr><td>Sterilization room</td><td></td><td></td></tr>
</table></td><td></td><td></td></tr>
<tr><td></td><td>Potentially infectious waste(i.e. blood soaked products, IV tubing with blood, tissue, POC) in appropriate containers</td><td></td><td></td></tr>
<tr><td></td><td>Disposal of sharps (i.e. needles, lancets, capillary tubes syringes with needles, used microscopic slides & cover slips, etc.) in appropriate sharp containers</td><td></td><td></td></tr>
<tr><td></td><td>Unexpired cleaning supplies & equipment accessible to staff</td><td></td><td></td></tr>
<tr><td></td><td>Clinic Procedure and Laboratory Practices Manual available to staff
Staff can identify how to access</td><td></td><td></td></tr>
<tr><td></td><td>Manufacturer’s equipment guidelines for operational usage on site for:
▪ Laboratory Equipment
▪ Decontamination & Sterilization Equipment</td><td></td><td></td></tr>
<tr><td></td><td>Proficiency Log in place for all staff, including staff whose job duties began in current month</td><td></td><td></td></tr>
<tr><td></td><td>Workstations free of hazards</td><td></td><td></td></tr>
</table>

Comments/Corrective Actions:

Manger of Surgical Services/Delegate Review Signature:

Name _____ **Title** _____ **Date**_____

At completion of audit and review by Manger of Surgical Services, form submitted to Director of Quality and Training.

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Emergency Box: Medications and Supplies for Surgical Services and Reproductive Health Services

Supplies
3cc -5cc Syringes
21g or 22g Needles
Alcohol preps
Tape, Plastic/paper
Nasal cannula
O2 mask
Oxygen tank with liter meter
Angiocath: 18g - 20g (IV)
Sterile 4 x 4 gauze
Exam gloves (non-latex)
Tourniquet
IV start kit
IV tubing
Ringers Lactate (LR) +/or Normal Saline (NS)
Endotracheal equipment: Laryngeal mask airway (LMA) Ambu bag
IV Bag 30 ml foley catheter Packing material
Suture kit
Yankauer
Saline flush

Medications
Diphenhydramine hydrochloride (Benadryl)
Epinephrine or EpiPen
Naloxone (Narcan) vial
Flumazenil (Romazicon)
Atropine Sulfate
Pitressin (Vasopressin) 20units/ml vial
Ammonia Capsules
Albuterol inhaler
Misoprostol

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1.1.20 Contraception After Surgical Abortion

I. Information regarding all methods of contraception should be offered, and, if requested, a method **must** be provided or referrals given for that method.

II. Providers are encouraged to provide contraception on day of procedure according to the following
   A. CHC
   B. DMPA
   C. Implant
   D. IUC
   E. POPs
   F. Prescription barriers
   G. Non-prescription Methods

✓ See Chapter 6 Contraception — Reversible

III. EC, a prescription for EC, and/or information describing how EC can be obtained should be given to each patient.

1.3 MANAGEMENT OF ABORTION COMPLICATIONS

✓ Refer to ARMS Emergency Manual for management of acute emergencies.

Important Information — When a Surgical Abortion Procedure Must be Completed on the Same Day

A procedure **must** be completed, either at the health center or by transfer to a hospital, under the following circumstances:

- Patient unstable
- Known retained fetal parts when gestational age > to 13 weeks, and onsite resources have been unsuccessful (e.g. misoprostol, oxytocin, consultation with a more experienced provider, etc.)
- Suspected complicated uterine perforation (e.g. second trimester, lateral perforation, evidence of visceral injury)
- Patient unable to return for additional care
- Patient preference

Under any other circumstances, the procedure may be stopped and the patient sent home to return on another day and/or to see another provider.

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Planned Parenthood of the St. Louis Region and Southwest Missouri
4251 Forest Park avenue, Saint Louis, MO 63108 (314)531-7526

Patient Services Orientation Checklist

Name_____Title _____ Date hired ____/____/____

Safety/Security	**Reviewed by**	**Date**	**Employee Initials**
1. Fire Procedures	_____	_____	_____
2. Evacuation Procedures	_____	_____	_____
3. Handling Threats via Phones & in Person	_____	_____	_____
4. Emergency-Numbers & Important Contacts	_____	_____	_____
5. Panic Button	_____	_____	_____
6. Emergency Exit	_____	_____	_____
7. Signature Log	_____	_____	_____
8. Workers Comp Procedures	_____	_____	_____
*to be done first day in center and then reviewed during next drill			
9. Staff sign in log	_____	_____	_____
10. Voluntary Participation Policy signed	_____	_____	_____

Medical Emergencies	**Reviewed by**	**Date**	**Employee Initials**
1. Personnel Responsibilities	_____	_____	_____
2. Communicating Emergencies (SBAR)	_____	_____	_____
3. Contacting Outside Resources (i.e. 911)	_____	_____	_____
4. CPR Certification	_____	_____	_____
5. Location & Use of Emergencies Equipment/Supplies	_____	_____	_____
6. MSDS Sheets	_____	_____	_____
7. SAB Sites Only-Crash Cart	_____	_____	_____
*to be done first day in center and then reviewed during next drill			

Infection Control	**Reviewed by**	**Date**	**Employee Initials**
1. Location/Review of OSHA Manual	_____	_____	_____
2. Review of Infection Control Policy	_____	_____	_____
3. Personal Protective Equipment & Eyewash Station	_____	_____	_____
4. Cleaning of Lab, Exam Rooms, U/S equipment, etc	_____	_____	_____

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Emergency Inventory Log Month: **2019**

PROCEDURE ROOM # ☐ **1** ☐ **2** ☐ **3**

(1) Each Unless Otherwise Indicated	Expiration Date	Date	Date	Date	Date	Date
Inspector (initials)*:						
Shelf # 1: Emergency Med. Kit, Saline Flush, Non-Sterile Gloves, Red Folder						
EMERGENCY MEDICATION KIT CONTENTS:						
Atropine 0.1mg/ml						
Diphenhydramine 50mg/ml						
Pitressin (Vasopressin) 20units/ml						
Naloxone 0.4mg/ml						
Flumazenil 1mg/10 ml						
Epi Pen 0.3mg						
Misoprostol 200mcg 4/btl						
50% Dextrose 25g/50mL						
(2) Normal Saline Flush						
3cc syringe w/ needle 21 x 1 (x3)						
Vaginal packing Guaze roll x 6						
Shelf #2: Foley Catheter, Drainage Bag, Catheterization Kit, IV Fluids, IV						
(2) Each Unless Otherwise Indicated	**Expiration Date**	**Date**	**Date**	**Date**	**Date**	**Date**
Inspector (initials)*:						
IV Admin. Set						
IVF Type: LR						
Size: ☐ 500 ml x2 **OR** ☐ 1L						
Drainage Bag						

-Continued-

(2) Each Unless	Expiration	Date	Date	Date	Date	Date

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Otherwise Indicated	**Date**					
Inspector (initials)*:						
22f/30ml Foley Catheter x 2						
30ml Prefilled Catheterization Kit x 2						
16f/30ml Urethral Catheter x 2						
10f/30ml All Purpose Urethral Catheter x 2						
Vicryl 2.0 stitch x 2						
Foley Drainage bag x 2						
Shelf #3: Oxygen Nasal Cannula, Oxygen Mask, Oral Airway						
Oxygen Nasal Cannula (2)	N/A					
Oxygen Mask (2)	N/A					
Ambu Bag (1)	N/A					
Suction Tubing	N/A					
Yankauer	N/A					

Visually Inspect To Ensure Functional/Clean

All shelves and items must be clean, dust, dirt and clutter free at all times. Do not store unauthorized items on cart or inside Emergency Kit. IMMEDIATELY report all expired medications to direct supervisor for replacement.

Print Name	Initials	Signature

*Initialing this audit tool indicates an audit was performed; all items were visualized and inspected. Each item is present, quantity and quality ensured at the time of inspection. Immediately report any issues to a clinic supervisor. _____ (sig)

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Emergency Inventory Log MONTH: **2019**

RECOVERY ROOM

(1) Each Unless Otherwise Indicated	Expiration Date *Grey fill indicates exp. date within 6 months	Date	Date	Date	Date	Date
Inspector (initials)*:						
Atropine 0.1mg/ml						
Diphenhydramine 50mg/ml						
Pitressin (Vasopressin) 20units/ml						
Naloxone 0.4mg/ml						
Flumazenil 1mg/10 ml						
Albuterol Inhaler (2)						
Epi Pen 0.3mg						
IVF 1000ml **OR** 500ml X2 ***indicate type***						
Dextrose 50% 0.5g/ml						
(3) Ammonia Inhalant						
0.9 Sodium Chloride 30ml						
(2) 20g IV Catheter						
(2) 18g IV Catheter						
(3) 21g Needle						
(3) 21g Safety Needle						
(3) 3cc Syringe w/needle						
(3) 5cc Syringe w/needle						
(3) 10cc Syringe w/o needle						

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Emergency Inventory Log MONTH: 2019

(1) Each Unless Otherwise Indicated	*Expiration Date* *Grey fill indicates exp. date within 6 months	Date	Date	Date	Date	Date
Inspector (initial)*:						
(3) Normal Saline Flush						
(2) IVF Admin. Set						
(3) IV Heplock						
(3) 23g Blood Collection						
Alcohol Prep Pads	N/A					
(3) Vacutainer	N/A					
(2) Tourniquet (Latex Free)	N/A					
Medical Tape	N/A					
Oxygen Mask	N/A					
Oxygen Nasal Cannula	N/A					
Non-Sterile Exam Gloves	N/A					
Yankauer						
Suction Tubing						
Suction Machine	N/A					
LMA						
Misc. Storage Section Items: Chucks, Emesis Bags, Drape Sheets, Arms Emergency Procedure Ref. Guide						

Print Name	Initials	Signature

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Emergency Inventory Log MONTH: **2019**

*Initialing this audit tool indicates an audit was performed; all items were visualized and inspected. Each item is present, quantity and quality ensured at the time of inspection. Immediately report any issues to a clinic supervisor.

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Reproductive Health Services of Planned Parenthood of the St. Louis Region

CONTROLLED SUBSTANCE ADMINSTRATION & DISPOSAL LOG

Patient Rm Number: Recovery Room

DRUG NAME & STRENGTH	Page #	BALANCE ON HAND	YEAR

DATE MRN PATIENT NAME PATIENT ADDRESS	AMT DISPENSED (vial)	AMT REC'D (ml)	AMT WASTED (ml)	REASON FOR WASTE: Full vial not given	REASON FOR WASTE: Other	Hour of disposal	BALANCE BROUGHT FORWAD	DISPENSER INITIALS	WITNESS INITIALS	PHYSICIAN NAME

Americans United for Life

DRUG NAME & STRENGTH	Page #	BALANCE ON HAND	YEAR

DATE MRN PATIENT NAME PATIENT ADDRESS	AMT DISPENSED (vial)	AMT REC'D (ml)	AMT WASTED (ml)	REASON FOR WASTE: Full vial not given	REASON FOR WASTE: Other	Hour of disposal	BALANCE BROUGHT FORWAD	DISPENSER INITIALS	WITNESS INITIALS	PHYSICIAN NAME

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 7, 2013

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00082492

Dear Jerome Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 25, 2013

Intake ID#: MO00082879

Dear Complainant:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under State Licensure Requirements for licensed abortion providers.

This complaint has been assigned ID MO00082879. We will review the information, and investigate the allegation(s) as appropriate for any regulatory violations. Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow State Licensing Requirements this agency will require corrective action to prevent further regulatory violations. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at BAC@health.mo.gov.

Sincerely,

John Langston, MBA
Administrator
Missouri Department of Health and Senior Services
Bureau of Ambulatory Care
BAC@health.mo.gov

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

February 10, 2016

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00111719

Dear Jerome Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 19, 2015

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00100367

Dear Jerome Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

HEALTH SERVICES REGULATION PHONE: 573/751-6303 FAX: 573/526-3621

June 20, 2011

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

RE: MO00071030

Dear Jerome Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Health Facility Regulation is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings.

We welcome any questions at 573-751-6303.

Sincerely,

Kathie Thomas

Kathie Thomas MN, RN
Health Facility Nursing Consultant
Bureau of Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

July 6, 2016

Mary Maschmeier
Founder/President
Defenders of the Unborn
P.O. Box 892
St. Charles, MO 63302-0892

Intake ID#: MO00114829

Dear Ms Maschmeier:

On July 6, 2016, the Bureau received copies of your letter dated June 15, 2016, addressed to the Missouri Board of Registration for the Healing Arts. We are reviewing the letter and will proceed accordingly.

If you have any questions, we can be reached at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

HEALTH SERVICES REGULATION PHONE: 573/751-6303 FAX: 573/526-3621

July 7, 2010

Mary Maschmeier
Defenders Of The Unborn
Po Box 892
St Charles, MO 63302

RE: MO00063750

Dear Mary Maschmeier:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***.

Health Facility Regulation is responsible for investigating complaints under Federal Regulations and State LIcensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems.

We welcome any questions at 573-751-6303.

Sincerely,

Beverly Rex

Beverly Rex, RN
Bureau Chief
Bureau of Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

HEALTH SERVICES REGULATION PHONE: 573/751-6303 FAX: 573/526-3621

July 10, 2009

Mary Maschmeier
Defenders Of The Unborn
Po Box 892
St Charles, MO 63302

RE: MO00054656

Dear Mary Maschmeier:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***.

Health Facility Regulation is responsible for investigating complaints under Federal Regulations and State LIcensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems.

We welcome any questions at 573-751-6303.

Sincerely,

Dean A. Linneman, MHA, MT (ASCP)
Section Director
Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

August 7, 2014

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109-3315

Intake ID#: MO00095990

Dear Jerome Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

September 17, 2013

Intake ID#: MO00088230

Dear Complainant:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

November 6, 2013

Jerome S. Jacobsmeyer
6767 Eichelberger St.
St. Louis, MO 63109-3315

Intake ID#: MO00089143

Dear Jerome S. Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at BAC@health.mo.gov.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
BAC@health.mo.gov

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

November 18, 2013

Mary Maschmeier
Defenders Of The Unborn
Po Box 892
St Charles, MO 63302

Intake ID#: MO00089716

Dear Mary Maschmeier:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at BAC@health.mo.gov.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

December 11, 2012

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00082026

Dear Jerome Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

February 20, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure & Complaint Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***January 31, 2013*** in connection with the ***State Licensure*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Americans
United
for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 29, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***March 16, 2016*** in connection with the ***State Licensure*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 14, 2015

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***March 31, 2015*** in connection with the ***State Licensure*** requirements and ***Medicare*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Enclosure

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 30, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains
711 N Providence Road
Columbia, MO 65203

RE: ***Licensure Survey TKOR11***

Dear Vicki Casey:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***August 14, 2018*** in connection with the ***State Licensure*** requirements as they pertain to abortion centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

January 4, 2019

Cathy Williams, SPHR, SHRM-SCP
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00151249***

Dear Cathy Williams:

The results of the recent complaint survey conducted at your facility on ***January 3, 2019*** indicate that your facility is in compliance with the State Licensure regulations for abortion centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-1588.

Respectfully,

Melinda Laughlin RN,BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosures

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

January 30, 2014

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

The results of the recent survey conducted at your facility on ***January 21, 2014*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

February 27, 2019

Janice Thomas
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00152740***

Dear Janice Thomas:

The results of the recent complaint survey conducted at your facility on ***February 11, 2019*** indicate that your facility is in compliance with the State Licensure regulations for abortion centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-1588.

Respectfully,

Melinda Laughlin RN,BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosures

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

March 21, 2018

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint #MO00140153***

Dear Mary Kogut:

The results of the recent survey conducted at your facility on ***March 19, 2018*** indicate that your facility is in compliance with the State Licensure regulations for abortion facilities.
Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 12, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint #MO00125526 Survey***

Dear Mary Kogut:

The results of the recent survey conducted on ***May 1, 2017*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 12, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00126207 Survey***

Dear Mary Kogut:

The results of the recent survey conducted on ***May 1, 2017*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 27, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00114829***

Dear Mary Kogut:

The results of the recent unannounced allegation survey conducted at your facility on ***May 17, 2016*** and continued off-site until ***May 25, 2016*** indicate that your facility is in compliance with the State Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

July 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Compaint # MO00116700***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff regarding your facility on ***July 12, 2016*** indicate that your facility is in compliance with the Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

August 5, 2014

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint MO00095990***

Dear Mary Kogut:

The results of the recent off site survey conducted on ***July 28, 2014*** indicate that your facility is in compliance with the State Licensure regulations CSR 30-20.060.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

August 17, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00131562***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***August 14, 2017*** and concluded on ***August 15, 2017*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

September 9, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00118398***

Dear Mary Kogut:

The results of the recent survey conducted at your facility from ***August 25, 2016*** through ***September 7, 2016*** indicate that your facility is in compliance with the State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

October 21, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00088230***

Dear Mary Kogut:

The results of the recent offsite complaint survey regarding your facility on ***September 19, 2013*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 9, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint MO00120615***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***November 7, 2016*** and concluded on ***November 8, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 16, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00121121***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***November 14, 2016*** and concluded on ***November 15, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 22, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Offsite Self Report Review***

Dear Mary Kogut:

An offsite investigation was conducted from ***01/11/16*** to ***01/12/16***. Please see attached results. Your facility was found to be in compliance with the ***Licensure*** requirements for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 27, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

The Plan of Correction is accepted in lieu of an onsite revisit. Please see attached results. This relates to the Licensure survey conducted on ***March 16, 2016*** and the revisit survey conducted on ***May 17, 2016***. Your facility is now in compliance with the ***Licensure*** requirements for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

October 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00119763***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***September 30, 2016*** and concluded on ***October 4, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

December 20, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey # MO00121661***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***December 7, 2016*** and concluded on ***December 19, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 21, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Revisit Survey***

Dear Mary Kogut:

Please see attached results of the recent follow-up survey of ***March 19, 2013***. This relates to the Licensure & Complaint survey conducted ***January 31, 2013***. Your facility is now in compliance with Licensure requirements for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 30, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00113026***

Dear Mary Kogut:

The results of the recent complaint survey conducted on ***March 23, 2016*** through ***March 28, 2016*** indicate that your facility is in compliance with the State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 30, 2018

Janice Thomas
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Revisit Survey***

Dear Janice Thomas:

Please see attached results of the recent follow-up survey of ***May 29, 2018***. This relates to the Licensure survey conducted ***March 7, 2018***. Your facility is now in compliance with the Licensure requirements for Abortion Facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

June 2, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Revisit Survey***

Dear Mary Kogut:

Please see attached results of the recent follow-up survey of ***May 31, 2017***. This relates to the Licensure survey conducted ***May 25, 2017***. Your facility is now in compliance with the Licensure requirements for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

June 15, 2015

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Revisit Survey***

Dear Mary Kogut:

Please see attached results of the recent follow-up survey of ***June 9, 2015***. This relates to the Licensure survey conducted ***March 31, 2015***. Your facility is now in compliance with the Medicare and Licensure requirements for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

September 8, 2017

Vicki Casey
Comprehensive Health of Planned Parenthood Great Plains, Inc.
711 N Providence Road
Columbia, MO 65203

RE: ***Licensure Revisit Survey***

Dear Vicki Casey:

Please see attached results of the recent follow-up survey of ***August 28, 2017***. This relates to the Licensure survey conducted ***October 11, 2016.*** The facility is now in compliance with the current legal requirements for licensure of abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

December 14, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains, Inc.
711 N Providence Road
Columbia, MO 65203

RE: ***Second Revisit Licensure Survey***

Dear Vicki Casey:

Please see attached results of the recent follow-up survey on ***December 6, 2018***. This relates to the Licensure Survey conducted ***August 14, 2018***. Your facility is now compliant with all deficiencies previously cited.

Abortions shall not be performed at CHPPGP until the facility is licensed and in compliance with all applicable laws, including but not limited to the hospital privileges requirements. *See* §§ 188.027, 188.080 & 197.215 RSMo; 19 CSR 30-30.060(1)(C)(4).

Please retain this material for your own records.

Please contact the Bureau of Ambulatory Care with any questions at 573-751-1588 or BAC@health.mo.gov.

Respectfully,

Melinda Laughlin RN, BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosure

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 19, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Revisit Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the revisit survey conducted on ***May 17, 2016*** in reference to the original survey of ***March 16, 2016*** in connection with the ***State Licensure*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

April 6, 2018

Janice Thomas
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Janice Thomas:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings (deficiencies) of the survey conducted on ***03/07/2018*** in connection with the Licensure Survey requirements as they pertain to ambulatory surgical centers in Missouri. Please submit a Plan of Correction (POC) stating how you will correct the cited deficiencies. This POC must be submitted within ten (10) calendar days of the date this letter and SOD is received by your facility.

An acceptable plan of correction must contain the following elements:

1. Address each deficiency individually, unless both State and Federal regulations have been cited. For example, A0405 and L1236 often address the same concerns. If the deficiency statement is identical, you may combine the citations and state one Plan of Correction.
2. The plan should state how you will improve the process that led to the deficiency cited. State each component, as indicated. For example, write facility policy, train staff on new process, etc.
3. The plan must include the monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected and /or in compliance with the regulatory requirements. The Plan must include frequency and length of monitoring and tracking procedures to ensure the plan of correction is effective.
4. The plan must include a date when each deficiency will be/has been corrected or completed. In general, we would expect the facility to have a corrective action fully implemented no later than 45 days after the Statement of Deficiencies was received. This date must include when the facility will be in full compliance.
5. Should you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include the expected completion date(s) for each phase. If the phased POC is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.
6. The plan must include the title of the person responsible for implementing and monitoring the plan of correction for each deficiency, and must state how the stated improvement actions will be incorporated into your Quality Assessment and Performance Improvement (QAPI) Program to reduce the likelihood of the deficient practice reoccurring.
7. The first page of the Form 2567 **for each set of regulations cited** must be signed and dated in the block labeled "Facility Representative's Signature."

Americans United for Life

Even though the deficiency may have been corrected before a Plan of Correction is returned to this office, the plan must be outlined as stated above. The statement "corrected" or "completed" is not an acceptable response. Your POC must specify how these deficiencies were corrected and the date of correction.

Please retain a copy of this letter and the SOD for your reference. We welcome any questions at (573) 751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Defenders of the Unborn
P.O. Box 892
St. Charles, MO 63302
www.stl-defenders.com

May 3, 2019
Investigation Unit
Board of Healing Arts

To Whom It May Concern:
Defenders of the Unborn has information that an ambulance was called to Planned Parenthood 4251 Forest Park Blvd. St. Louis, MO to transport a patient to an area hospital on April 24, 2019. Responding to the call was St. Louis Ambulance.

The paramedics were seen removing an African American woman who was strapped to the stretcher. We ask that a full investigation be conducted to insure that excellent medical care is given to all patients.

It is our understanding that the abortionist who was present on that day was either Colleen McNicholas or Tess Madden.

Since 2009, 71 medical emergencies have been reported. This request for an ambulance makes 72-911 call to this location.

Defenders of the Unborn thanks you for your time in this vital matter to ensure quality healthcare for women. It is paramount that doctors are qualified to perform surgical procedures. With this number of ambulances it is concerning that they are not qualified to perform surgical procedures.

Defenders of the Unborn can be reached at 314-346-9052 or email defenseless68@gmail.com
Our mailing address is 13610 Barrett Office Dr. Suite 203 Manchester, MO 63021

Sincerely,
Mary Maschmeier
Mary Maschmeier-
Founder/President
Defenders of the Unborn

c.c. Missouri Health Department
c.c. U.S. Congresswoman Ann Wagner

RECEIVED MAY 14 2019

Americans United for Life

c.c. President Donald Trump
c.c. U. S. Senator Roy Blunt
c.c. Governor Mike Parson
c.c. U.s Senator Josh Hawley
c.c. Attorney General Eric Schmitt
c.c. Alderman Joseph Rody
c.c. Alderman Joseph Vacarro
c.c. Rep. Chrissy Sommer

Americans United for Life

Defenders of the Unborn
P.O. Box 892
St. Charles, MO 63302
www.stlabortions.com

May 3, 2019
Investigation Unit
Board of Healing Arts

To Whom It May Concern:
On Friday April 26, 2019, a 911 call was made from Planned Parenthood 4251 Forest Park Blvd. St. Louis, MO for a medical emergency. Responding to the call was the St. Louis City Ambulance. The ambulance arrived at 2:30 p.m. The patient was transported to an area hospital for care.

This call is the second call in one week. On Wednesday April 24, 2019, an ambulance was called for another medical emergency from this same location. It is without a doubt that this surgical provider is not qualified to perform medical procedures. This call is the 73rd. call made since 2009. With some calls in the same week. The abortionist was Tesse Madden.

We are requesting a full investigation of this facility. We ask that this clinic be closed to ensure quality investigation. We must stop the continual 911 calls to this medical provider. We ask that you be objective in this urgent need to ensure that women receive the quality care that they deserve.

Defenders of the Unborn thanks you for your time in the vital matter to protect women to allow them to have quality healthcare. We await your response

Sincerely,

Mary Maschmeier

Mary Maschmeier- Founder/President
Defenders of the Unborn

c.c. President Donald Trump
c.c. Missouri Health Department
c.c. U.S. Congresswoman Ann Wagner
c.c. U.S. Senator Roy Blunt
c.c. U.S. Senator Josh Hawley
c.c. Governor Mike Parson
c.c. Attorney General Eric Schmitt

Americans United for Life

c.c. Alderman Joseph Roddy
c.c. Alderman Joseph Vacarro
c.c. Rep. Chrissy Sommer
c.c. Circuit Attorney City of St. Louis- Kim Gardner

Americans
United
for Life

Missouri Department of Health and Senior Services
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 7, 2013

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00082492

Dear Jerome Jacobsmeyer:

The Bureau of Ambulatory Care (BAC) has reviewed your concerns involving ***Reporductive Health Services/Planned Parenthood*** in ***St. Louis, MO.***

The same issue(s) were investigated by the Bureau of Health Services Regulation in July 2011; no regulatory violations were found as a result of the investigation. With no new information provided that would document a licensure violation, this allegation will be closed without additional action at this time, pending a routine licensure survey of the facility this year

The Bureau of Ambulatory Care considers all complaints seriously and thoroughly reviews concers brought to our attention. Thank you for taking the time and making the effort of bringing your concerns to our attention.

We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

January 10, 2014

Brittany Pyatt
430 Chaparrall Creek Dr Apt 2602
Hazelwood, MO 63042

Intake ID#: MO00089143

Dear Brittany Pyatt:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

If your complaint was found to be:

> **Unsubstantiated** - *The surveyor thoroughly investigated all aspects of the complaint, but could not identify violations under Federal or State Requirements, and therefore deficiencies were not cited. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated (proven) or it is not related to Federal or State Regulations.*

We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

January 15, 2015

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00100367

Dear Jerome Jacobsmeyer:

We received your complaint regarding your concerns with ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO***. Bureau of Ambulatory Care is responsible for investigating complaints under Federal Regulations and State Licensure Requirements.

Please be assured that if during the course of our investigation it is found that ***Reproductive Health Services / Planned Parenthood*** failed to follow Federal Regulations and/or State Licensing Requirements this agency will utilize its authority to effect a change that will prevent someone else from experiencing similar problems. Upon completion of our investigation, you will receive notice of the findings. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 22, 2016

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00110832

Dear Jerome Jacobsmeyer:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility. Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable State Regulations. Based upon our investigation the complaint was found to be ***unsubstantiated***.

The investigation included review of medical records and applicable policies and procedures. Based on this investigation, it was determined the facility met all applicable regulations. The facility is in compliance with State Regulations at this time.

Thank you for bringing your concerns to our attention. We welcome any questions at 573-751-6303.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

January 28, 2014

Mary Maschmeier
Defenders Of The Unborn
Po Box 892
St Charles, MO 63302

Intake ID#: MO00089716

Dear Mary Maschmeier:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

If your complaint was found to be:

> **Unsubstantiated** - *The surveyor thoroughly investigated all aspects of the complaint, but could not identify violations under Federal or State Requirements, and therefore deficiencies were not cited. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated (proven) or it is not related to Federal or State Regulations.*

We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Americans
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for Life

Missouri Department of Health and Senior Services
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 21, 2013

Intake ID#: MO00082879

Dear Complainant:

Recently an inspection team from the Department of Health & Senior Services' Bureau of Ambulatory Care conducted an unannounced inspection of Reproductive Health Services/Planned Parenthood of St Louis (RHS/PPSL).

The primary purpose of our visit was to conduct an investigation into the issues raised in your complaint brought to our attention regarding emergency transfer of patients via ambulance from RHS/PPSL to local hospitals.

In addition, our inspection staff also conducted a complete licensure survey to ensure compliance with all regulatory requirements of 19 CSR 30-30.060 Organization and Management for Abortion Facilities.

Our inspection included review of administrative oversight, appropriate medical and nursing care, infection control, the physical environment, quality assurance, and content of records.

Although issues with state licensure rules were cited, none of the deficiencies were regarding emergency transfer of patients. We reviewed all medical records of patients receiving emergency transfers to hospitals within the recent past, in addition to a sample of other records. When measured against the state licensure standards, our review indicated that patients received adequate medical oversight, and the transfers were medically appropriate under the circumstances.

We thank you for the concern you expressed for the healthcare services provided to these patients. Our bureau will continue to conduct periodic inspections to ensure regulatory compliance with all applicable state licensure rules. If you have future new concerns with the facility, you may file a formal complaint with our bureau at BAC@health.mo.gov or the address listed below.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Americans
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for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 24, 2016

Mary Maschmeier
Founder/President
Defenders of the Unborn
P.O. Box 892
St. Charles, MO 63302

Intake ID#: MO00110832

Dear Mary Maschmeier:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility.

Our surveyor investigated all aspects of the complaint to determine compliance with applicable State Regulations. Based upon our investigation the complaint was found to be ***unsubstaniated***.

Thank you for bringing your concerns to our attention. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 23, 2015

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00100367

Dear Jerome Jacobsmeyer:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

If your complaint was found to be:

Unsubstantiated - *The surveyor thoroughly investigated all aspects of the complaint, but could not identify violations under Federal or State Requirements, and therefore deficiencies were not cited. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated (proven) or it is not related to Federal or State Regulations.*

We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

July 12, 2016

Mary Maschmeier
Founder/President
Defenders of the Unborn
P.O. Box 892
St. Charles, MO 63302-0892

Intake ID#: MO00114829

Dear Mary Maschmeier:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns about this facility addressed to the Missouri Board of Registration, dated June 15, 2016 and received by our office July 6, 2016.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable State Regulations. Based upon our investigation the complaint was found to be Unsubstantiated. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated (proven) or it is not related to State Regulations.

We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

Health Services Regulation Phone: 573/751-6303 Fax: 573/526-3621

July 21, 2011

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Case No. ***MO00071030***

Dear Jerome Jacobsmeyer:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in *Saint Louis* regarding your concerns at this facility.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

If your complaint was found to be:

> ***Substantiated -*** *A Statement of Deficiencies (CMS-2567) and/or (MO-2567) citing the deficiencies has been sent to the facility. The facility will be required to submit a Plan of Correction to us describing how those deficiencies will be corrected. If the facility was found to be in compliance, a compliance statement (CMS-2567) and/or (MO-2567) has been sent to the facility.*
>
> ***Unsubstantiated -*** *The surveyor thoroughly investigated all aspects of the complaint, but could not identify violations under Federal or State Requirements, and therefore deficiencies were not cited. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated (proven) or it is not related to Federal or State Regulations.*

We welcome any questions at 573-751-6303.

Sincerely,

Kathie Thomas

Kathie Thomas MN, RN
Health Facility Nursing Consultant
Bureau of Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

August 5, 2014

Mary Maschmeier
Defenders Of The Unborn
Po Box 892
St Charles, MO 63302

Intake ID#: MO00095990

Dear Mary Maschmeier:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

If your complaint was found to be:

> **Unsubstantiated** - *The surveyor thoroughly investigated all aspects of the complaint, but could not identify violations under Federal or State Requirements, and therefore deficiencies were not cited. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated (proven) or it is not related to Federal or State Regulations.*

We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Americans
United
for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

August 7, 2014

Jerome S Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109-3315

Intake ID#: MO00095990

Dear Jerome S Jacobsmeyer:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

If your complaint was found to be:

> **Unsubstantiated** - *The surveyor thoroughly investigated all aspects of the complaint, but could not identify violations under Federal or State Requirements, and therefore deficiencies were not cited. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated (proven) or it is not related to Federal or State Regulations.*

We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

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for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

Health Services Regulation Phone: 573/751-6303 Fax: 573/526-3621

August 14, 2009

Mary Maschmeier
Defenders Of The Unborn
Po Box 892
St Charles, MO 63302

Case No. ***MO00054656***

Dear Mary Maschmeier:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in *Saint Louis* regarding your concerns at this facility.

Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

If your complaint was found to be:

> ***Substantiated -*** *A Statement of Deficiencies (CMS-2567) and/or (MO-2567) citing the deficiencies has been sent to the facility. The facility will be required to submit a Plan of Correction to us describing how those deficiencies will be corrected. If the facility was found to be in compliance, a compliance statement (CMS-2567) and/or (MO-2567) has been sent to the facility.*
>
> ***Unsubstantiated -*** *The surveyor thoroughly investigated all aspects of the complaint, but could not identify violations under Federal or State Requirements, and therefore deficiencies were not cited. This does not mean that your concerns are not valid, it only means that either the complaint could not be substantiated or it is not related to Federal or State Regulations.*

We welcome any questions at 573-751-6303.

Sincerely,

Dean A. Linneman, MHA, MT (ASCP)
Section Director
Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

October 16, 2013

Intake ID#: MO00088230

Dear Diane Foland:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns about inappropriate emergency transfers at this facility. Our surveyor thoroughly investigated all aspects of the complaint to determine compliance with all applicable Federal and State Regulations. Based upon our investigation the complaint was found to be ***Unsubstantiated***.

The investigation included interviews and review of medical records and applicable policies and procedures. Based on this investigation, it was determined the facility met all applicable regulations. The facility is in compliance with State Regulations at this time.

Thank you for bringing your concerns to our attention. We welcome any questions at BAC@health.mo.gov.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 18, 2016

Mary Maschmeier
Founder/President
Defenders of the Unborn
P.O. Box 892
St. Charles, MO 63302-0892

Intake ID#: MO00120615

Dear Mary Maschmeier:

This is to inform you that a complaint investigation was conducted involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis*** regarding your concerns at this facility.

Our surveyor investigated all aspects of the complaint to determine compliance with applicable State Regulations. Based upon our investigation the complaint was found to be ***unsubstaniated***.

Attached is a copy of the investigation record. Before receiving your complaint, the department investigated an identical complaint; that is why the inspection record predates your complaint.

Thank you for bringing your concerns to our attention. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

March 5, 2018

Reproductive Health Services / Planned Parenthood
Janice Thomas
4251 Forest Park Avenue
St. Louis, MO 63108

Intake ID#: MO00139789

Dear Janice Thomas:

We received your self-report regarding visitor transport on February 24, 2018, and after careful review, we have determined the issue(s) brought to our attention does not involve a regulatory requirement under State regulation. Therefore, we will not conduct an investigation at this time.

Please feel free to contact our office if you have additional information or concerns that would help us to re-evaluate our decision. We welcome any questions at 573-751-6083.

Regards,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

November 30, 2010

Mary Maschmeier
Defenders Of The Unborn
Po Box 892
St Charles, MO 63302

Case No. # MO00063750

Dear Mary Maschmeier:

We received your complaint against ***Reproductive Health Services / Planned Parenthood,*** and after careful review, we have determined the issue(s) brought to our attention does not involve a regulatory requirement under State and/or Federal regulation. Therefore, we will not conduct an investigation at this time.

Please feel free to contact our office if you have additional information or concerns that would help us to re-evaluate our decision. We welcome any questions at 573-751-6303.

Regards,

Kathie Thomas

Kathie Thomas MN, RN
Health Facility Nursing Consultant
Bureau of Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

July 21, 2011

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

Case No. ***MO00071030***

Dear Mary Kogut:

This is to inform you that an off-site medical record review was conducted on your facility under the State Licensure regulations in response to a complaint we received. Based on this review, we find your facility to be in substantial compliance with CSR30.20.021 as it relates to ***MO00071030*** and no deficiencies are cited.

Please retain this letter for your files.

We welcome any questions at 573-751-6303.

Sincerely,

Kathie Thomas

Kathie Thomas MN, RN
Health Facility Nursing Consultant
Bureau of Health Services Regulation

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 7, 2013

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00082492

Dear Jerome Jacobsmeyer:

The Bureau of Ambulatory Care (BAC) has reviewed your concerns involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO*** and we want to inform you that BAC surveyors have been on-site recently to assess this facility's compliance with regulatory requirements involving patient care and services. Corrective actions have been taken where appropriate to assure patient safety and to prevent the recurrence of deficient practice in the future. Therefore, we will not take any additional actions at this time.

The Bureau of Ambulatory Care considers all complaints seriously and thoroughly reviews concerns brought to our attention. Thank you for taking the time and making the effort of bringing your concerns to our attention. We welcome any questions at 573-751-6083.

Sincerely,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

December 11, 2012

Jerome Jacobsmeyer
6767 Eichelberger St
St Louis, MO 63109

Intake ID#: MO00082026

Dear Jerome Jacobsmeyer:

The Bureau of Ambulatory Care (BAC) has reviewed your concerns involving ***Reproductive Health Services / Planned Parenthood*** in ***Saint Louis, MO.***

The same issue(s) were investigated by the Bureau of Health Services Regulation in July 2011; no regulatory violations were found as a result of the investigation. With no new information provided that would document a licensure violation, this allegation will be closed without additional action at this time, pending a routine licensure survey of the facility in the upcoming year.

The Bureau of Ambulatory Care considers all complaints seriously and thoroughly reviews concerns brought to our attention. Thank you for taking the time and making the effort of bringing your concerns to our attention. We welcome any questions at 573-751-6083.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 1, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***PoC Approval***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Licensure & Complaint Survey conducted on ***January 31, 2013*** has been received in our office and forwarded to the surveyor(s). We want you to know the surveyor(s) has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 30, 2015

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***POC Approval***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Licensure Survey conducted on ***March 31, 2015*** has been received in our office and forwarded to the surveyor(s). We want you to know the surveyor(s) has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 3, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***PoC Approval***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Licensure Survey Survey conducted on ***March 16, 2016*** has been received in our office and forwarded to the surveyor(s). We want you to know the surveyor(s) has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

April 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***PoC Rejection***

Dear Mary Kogut:

On April 7, 2016 our Bureau received your Plan of Correction as a result of a Licensure Survey conducted March 16, 2016. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

L1128 -

- #1-Will the autoclaves be professionally cleaned to return the chambers to a satisfactory condition? Please include any re-education of staff on following manufacturer's instructions. Please confirm and provide documentation.
- #3-Please include the document referenced in the plan of correction titled, "Spore Testing Biological Indicator," and include staff education on following manufacturer's instructions.
- #5-Are all formerly processed instruments done incorrectly being reprocessed? Please confirm and provide documentation.
- #6-If available, include the document referenced in the plan of correction titled, "Pharmaceutical Services."
- #7-Training should be specific to single-dose vials (this was copied from #6's multi-dose vials). If available, include the document referenced in the plan of correction titled, "Pharmaceutical Services."
- Glucometer-When the new multi-patient use glucometers are purchased, will the facility update their current policy to include instructions for cleaning **and** disinfecting the glucometer or to follow manufacturer's guidelines?

L1137-

- CBC's – The criminal background checks need to be completed for the three volunteers currently staffed at the facility.
- EDL's – Please include a plan for periodic EDL verifications. Also, the EDL's need to be completed for the three volunteers currently staffed at the facility. The plan of correction does not mention monitoring for EDL verification compliance (it says CBC in the EDL plan of correction area).

L1153 -
Please include the documents referenced in the plan of correction titled, "Pharmaceutical Services" (also referenced in L1128 #6), "RHS Patient Orders", and "RHS-PPSLR Standing Orders."

L1165 -
Please include the document referenced in the plan of correction titled, "Pre-op & Post-op Patient Documentation."

Please submit a revised Plan of Correction with the above mentioned information within five (5) calendar days from the receipt of this notice via email to BAC@health.mo.gov or fax to (573) 751-6158 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083 Fax: 573-751-6158

Americans United for Life

Americans
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for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

April 27, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***2nd PoC Rejection***

Dear Mary Kogut:

On April 12, 2016 our Bureau received your Plan of Correction as a result of a Licensure Survey conducted March 15, 2016. Your Plan of Correction is unacceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

L1128 –
#3 – The document titled, "ARMS Infection Control Manual," continues to require a minimum weekly spore test, or possibly daily. The manufacturer's instructions for the Attest show they are to be used with every load. Your ARMS Infection Control Manual references CDC's guidance for oral health. Your abortion facility does not provide dental services. The plan of correction includes multiple nationally-recognized standards of which your facility does not follow (Example: American Dental Association). Per ANSI/AAMI ST79, "All BIs should be used in accordance with the BI manufacturer's written instructions." Either the Infection Control Manual needs changed to reflect the manufacturer's instructions or a different product must be used to accommodate your policy of a weekly or daily spore test. We would encourage you to select a nationally-recognized standard that is relevant to surgical services in general, not dental.

Please submit a revised Plan of Correction with the above mentioned information within ten (10) calendar days from the receipt of this notice via email to BAC@health.mo.gov or fax to (573) 751-6158 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 24, 2018

Christine South
Comprehensive Health Of Planned Parenthood Great P
1001 Emanuel Cleaver Ii Blvd
Kansas City, MO 64110-1687

RE: ***PoC Rejection***

Dear Christine South:

On July 30, 2018 our Bureau received your Plan of Correction as a result of a Licensure Survey Survey conducted June 21, 2018. Your Plan of Correction is unacceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

L1081:
Please verify that staff participation in fire and disaster drills will not occur until 09/13/18.

L1084:
Staff names used multiple times. Please remove staff names and use titles only as per the instructions on the Plan of Correction form (#3D.)
Correction dates too distant (08/15/2018 example 2)

L1090:
Staff name used, please use staff titles.
POC refers to past compliance not current compliance. Current compliance can only be evaluated when the facility has current abortion patients/procedures. How will the facility ensure when patient care is provided compliance will be maintained?

L1104:
Staff name used, please replace names with job titles.
PoC refers to past compliance not current compliance. This can't be evaluated until they have current abortion patients/procedures. How will the facility ensure when patient care is provided compliance will be maintained?
PoC shows the ultrasound machine will be returned when services are resumed. How will the facility verify to our office that the ultrasound has been returned or will be provided to patients as required and the equipment functions properly as verified typically by bio-med? This can't be evaluated until they have current abortion patients/procedures.

L1109:
At the time of survey the facility's process for documenting that discharge instructions were provided was not sufficient to meet the regulatory requirement.
Please refer to 19 CSR 30-30.050:
(3)(B) The facility shall maintain a medical record according to professional standards for each patient. (3)(D) The medical record shall contain...clinical notes, counseling notes.
The professional standard for medical records is to include a copy of the discharge instructions provided to patients. Please provide a plan for inclusion of the discharge instructions in the medical record.

L1118
The surveyors were presented with a computer generated list of patients that was based on a query of billing codes for abortion services. The list did not include the reason for the visit, and included non- abortion patients and was determined only through chart review.
Please show how the facility will maintain a daily roster of patients receiving abortion services.

L1122
Please provide the facility's plan to ensure that the required information and counseling is provided to patients by a physician or other qualified professional as required by Missouri law RSMo 188.027.

Please submit a revised Plan of Correction with the above mentioned information within five (5) calendar days from the receipt of this notice via email to BAC@health.mo.gov or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

September 13, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains, Inc
711 N Providence Road
Columbia, MO 65203

RE: ***PoC Rejection TKOR***

Dear Vicki Casey:

On September 10, 2018 our Bureau received your Plan of Correction as a result of a Licensure Survey Survey conducted August 14, 2018. Your Plan of Correction is unacceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

The facility has requested that the license not be allowed to lapse. To help ensure that, would the facility be able to implement any of the corrective actions sooner than the dates listed for tags L1084 and L1130?

L-1119 How will the facility ensure a copy of the discharge instructions will be included in the patient's medical record, consistent with current standards for medical record keeping.

L-1120 On what date does the facility expect the physician order document to be approved and implemented as the response only states in process.

L-1124 At the time of survey the state mandated reports were not included in two of the ten medical records reviewed and were not submitted to the survey team as available for the medical record. Going forward, how will the facility ensure the state mandated reports are included in the patients' medical record.

For 1130: Does the hand hygiene/glove use training include the physician?

Please submit a revised Plan of Correction with the above mentioned information within five (5) calendar days from the receipt of this notice via email to BAC@health.mo.gov or fax to (573) 751-6648 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Americans
United
for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director

Jeremiah W. (Jay) Nixon
Governor

July 21, 2011

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

Case No. ***MO00071030***

Dear Mary Kogut:

This is to inform you that an off-site medical record review was conducted on your facility under the State Licensure regulations in response to a complaint we received. Based on this review, we find your facility to be in substantial compliance with CSR30.20.021 as it relates to ***MO00071030*** and no deficiencies are cited.

Please retain this letter for your files.

We welcome any questions at 573-751-6303.

Sincerely,

Kathie Thomas

Kathie Thomas MN, RN
Health Facility Nursing Consultant
Bureau of Health Services Regulation

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	C 07/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Hospitals at CSR 30-20. The complaint is unsubstantiated with no deficiencies. #MO00071030- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.	L 000		

Missouri Department of Health and Senior Services

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	MOA-0014	A. BUILDING: _____ B. WING _____	C 12/11/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Hospitals at CSR 30-20. The complaint is unsubstantiated with no deficiencies. #MO00082026- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.	L 000		

Missouri Department of Health and Senior Services

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L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Hospitals at CSR 30-20. The complaint is unsubstantiated with no deficiencies. #MO00082492- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

February 20, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure & Complaint Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***January 31, 2013*** in connection with the ***State Licensure*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An on-site, unannounced allegation survey was conducted at this facility from 01/30/13 - 01/31/13. Complaint MO00082879. A state licensure inspection was conducted in conjunction with the allegation survey. The complaint (MO00082879) was found to be unsubstantiated. Deficiencies as a result of the licensing inspection are as follows:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on employee personnel file review, and review of the state statute, the facility failed to perform periodic Employee Disqualification List (EDL) checks on three of three employee personnel files reviewed. The facility does an average of 340 cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. EDL checking requirements are as follows: Section 660.315, RSMo Entities required to check the EDL: 1. Licensed as operator under Chapter 198; 2. Provides in-home services under contract with the department; 3. Temporary nurse staffing agencies;	L1111		

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L1111	Continued From page 1 4. Licensed under Chapter 197 (hospitals, ambulatory surgical centers, hospices, home health agencies); and 5. Public or private facility, day program, residential facility or specialized service operated, funded or licensed by the department of mental health. Under Section 660.315, these entities are prohibited from knowingly hiring a person, for any type of position, whose name appears on the EDL. These entities must, at a minimum, check the latest EDL (on the website after September of 2005) with updates before hiring any person for any job. 2. During an interview on 01/31/13 at 10:05 AM, Staff C, Vice President of Human Resources, stated that the facility did not do EDL checks for any of the staff currently working in the facility.	L1111		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on observation, interview, policy review,	L1128		

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L1128	Continued From page 2 and review of nationally recognized standards of practice, the facility failed to: -Ensure single use medications were discarded after use on each patient (used for multiple patients); -Ensure expired medications were available for patient use; -Date multi-dose vials when they are opened; -Ensure expired items were not available for patient use; -Ensure a sanitary environment was preserved by failure to replace worn, rusted or deteriorating equipment with functional easily cleanable surfaces that will not harbor and transmit infections in three of three Procedure Rooms; and -Ensure the facility was free of dust/debris in three of three Procedure Rooms, the storage room and supply room. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Record review of the Centers for Disease Control and Prevention (CDC) Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care, dated 05/11, showed the following: - Do not administer medications from single-dose or single-use vials, ampoules, or bags or bottles of intravenous solution to more than one patient. 2. Observation on 01/30/13 at 11:05 AM of the narcotic cabinet showed one opened 50 millimeter (ml) single dose vial of Fentanyl (pain medication) dated as opened on 01/27/13 with initials of the nurse who had opened the vial. The label on the medication stated, "single dose -	L1128		

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L1128	Continued From page 3 destroy unused contents, preservative free". 3. During an interview on 01/30/13, at the time of the observation, Staff K, Clinical Manager stated that the vials were used for more than one patient due to a shortage of the medication and the amount of waste that would result if the vial was disposed of after one use. 4. During an interview on 01/30/13 at 4:00 PM, Staff A, Vice President of Patient Services stated that the facility did not have a policy specific to single dose medication. 5. Review of the facility's policy titled, "Pharmaceutical Services", revised 12/12/12 shows: -At least monthly, supervisory staff should review the inventory to ensure that stock was being properly rotated and had not expired in all pharmaceutical storage areas; -Expired inventory must be removed from active stock. 6. Observation on 01/30/13 at 9:30 AM of emergency supplies in Procedure Room #1 showed: -One bag of Lactated Ringer (IV solution), expired 12/12. 7. During an interview on 01/30/13 at 9:45 AM, Physician D, Medical Director stated that medications and supplies were checked monthly by facility staff. 8. Observation on 01/30/13 at 10:11 AM of a cabinet in Procedure Room #2 showed: -One box of ammonia inhalant (used to prevent or treat fainting), three count, expired 05/10.	L1128		

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L1128	Continued From page 4 9. Observation on 01/30/13 at 10:45 AM of the narcotic cabinet behind the nursing station showed: -Nine vials of Valium (medication used for sedation), expired 12/01/12; -Eighteen vials of Naloxone Hydrochloride (used to counter the effects of a narcotic overdose), expired 10/12; and -Two 50% Dextrose (glucose) injectables, expired 08/12. 10. Observation on 01/30/13 at 11:10 AM of the emergency medications located in the pre-operative area showed: -One bag of Lactated Ringer expired 12/12. 11. During an interview on 01/30/13 at 11:15 AM, Staff K stated that nursing staff checked for expired medications weekly. (Note that this conflicts with Physician D's interview above, in regard to how frequently medications are checked). 12. During an interview on 01/31/13 at 10:45 AM, Staff A stated that nursing staff were responsible for checking monthly for expired medications. 13. Record review of the Centers of Disease Control and Prevention (CDC) recommendations for multi-dose vials, dated 02/09/11 showed: - When should multi-dose vials be discarded? Medication vials should always be discarded whenever sterility is compromised or questionable. In addition, the United States Pharmacopeia (USP) General Chapter 797 [16] recommends the following for multi-dose vials of sterile pharmaceuticals: - If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated	L1128		

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L1128	Continued From page 5	L1128		

and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.
The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer's original expiration date.

14. Review of the facility's policy titled, "Pharmaceutical Services", revised 12/12/12 showed:
-If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial must be dated and discarded in accordance with manufacturer's instructions and state/local regulations.

15. Observation on 01/30/13 at 9:25 AM of Procedure Room #1 showed one opened multi-dose vial of Lidocaine with no date to show when the vial was opened.

During an interview on 01/30/13, at the time of the observation, Staff L, Registered Nurse (RN) stated that she had just opened the vial that morning and she would discard it at the end of the day.

16. Review of the facility's policy titled, "Medical Equipment and Supplies", showed:
-Supplies are checked regularly by the assigned staff, rotated to ensure oldest used first, and;
-Expired supplies were removed from the active

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L1128	Continued From page 6 stock. 17. Observation on 01/30/13 at 10:35 AM of the supply room showed: -Three boxes of surgical gloves, expired 11/05; -One box of surgical gloves, expired 01/07, and; -Three postpartum balloons (used to control or reduce postpartum [occurring in the period shortly after childbirth] hemorrhage), expired 12/10, 12/11, and 01/12. 18. During an interview on 01/31/13 at 10:45 AM, Staff A stated that the policy needed to include the frequency that supplies were checked. 19. Review of the Association of Perioperative Registered Nurses (AORN) Standards and Recommended Practices, "Environmental Cleaning", dated 2012, Recommendation II showed, "A safe, clean environment should be reestablished after each surgical procedure. Routine cleaning and disinfection reduces the amount of dust, organic debris (debris in the environment) and microbial load (number and type of microorganisms contaminating an object) in the environment. Following scientifically based recommendations for cleaning and disinfection practice in health care organizations helps to reduce infections associated with contaminated items". 20. Review of the facility's policy titled, "Cleaning, Disinfection and Sterilization", revised 04/08 showed: -Thoroughly clean all surfaces that are being used in patient care areas. and; -All areas of the clinic should be kept clean and free from excess clutter. 21. Observation on 01/30/13 at 9:30 AM of	L1128		

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L1128	Continued From page 7 Procedure Room #1 showed: -One ceiling air vent that had copious amounts of visible dust/dirt; -One table with rusted castors (uncleanable surface); -One stool with rust which was covered with clear tape (uncleanable surface); -One plastic bin which contained emergency supplies was covered with dust; -One plastic bin which contained intravenous (IV/inserted into a blood vein) solution was covered with dust; and -One oxygen tank with adhesive residue (uncleanable surface). During an interview on 01/30/13 at 9:40 AM, Physician D, Medical Director acknowledged the dust on the plastic bins and stated that staff should have noticed when checking the emergency supplies. 22. Observation on 01/30/13 at 10:11 AM of Procedure Room #2 showed: -One ceiling air vent that had copious amounts of visible dust/dirt; -One IV pole with rusted castors; -One table with rusted castors; -One oxygen tank with rust and tape residue; -One suction machine with rust on the kick plates; -One plastic bin containing emergency supplies was covered with dust; and -One stool with rust which was covered with clear tape. 23. Observation on 01/30/13 at 10:25 AM of Procedure Room #3 showed: -Rust on the base of the procedure table; -One IV pole with rusted castors; -One table with rusted castors; -One oxygen tank with tape residue;	L1128		

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L1128	Continued From page 8 -One suction machine with rust on the sides; and -Two plastic bins containing emergency supplies were covered with dust. 24. Observation on 01/30/13 at 10:35 AM of the storage room showed: -One ceiling air vent with visible dust; and -The floor in the room which contained eight oxygen canisters had visible dirt and dust. 25. Observation on 01/30/13 at 10:45 AM of the supply room showed: -One suction machine with visible dust. 26. During an interview on 01/31/13 at 10:45 AM, Staff A stated that the management team was responsible for spot audits and for checking for environmental issues.	L1128		
L1170	19 CSR 30-30.060(3)(J) Each abortion facility shall develop Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following: 1. Completeness of clinical records; 2. Incidence of morbidity and mortality; 3. Intraoperative and postoperative complications; 4. All cases transferred to a hospital; 5. All cases that resulted in a length of stay of more than twelve (12) hours; 6. Errors in diagnosis;	L1170		

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L1170	Continued From page 9 7. Problems in compliance with state and local laws and regulations; and 8. All cases in which the gestational age was determined to be beyond eighteen (18) weeks. This regulation is not met as evidenced by: Based on interview and record review, the facility failed to adequately include in the Quality Assurance program all cases in which the gestational age was determined to be beyond eighteen (18) weeks. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of the facility's quarterly Quality Assurance (QA) log of complications and occurrences included the gestational age of the fetus as part of the data, but not all cases greater than 18 weeks were placed on the report. 2. During an interview on 01/30/13 at 4:45 PM, Staff A, Vice President of Patient Services confirmed that a gestational age of 18 weeks is not by itself considered a complication or occurrence, and therefore not all of those cases are routinely reviewed as part of the QA activities, only if there were also a complication and/or occurrence.	L1170		
L1171	19 CSR 30-30.060(3)(K) The quality assurance program must show The quality assurance program must show evidence of action taken as a result of the identification of the problems. This regulation is not met as evidenced by:	L1171		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1171	Continued From page 10 Based on interview and record review, the facility failed to adequately document action taken as a result of ongoing Quality Assurance activities. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of facility's quarterly Quality Assurance (QA) committee meeting notes indicated that while various improvement topics were discussed, there was no formal evidence presented to consistently indicate what actions were taken by the committee as a result of identification of problems. 2. During an interview on 01/30/13 at 3:50 PM Staff A, Vice President of Patient Services stated that the QA staff had many years of experience working together, knew each other well, and regularly talked about what issues were ongoing, but formal documentation of action items and the outcome could be improved. 3. During an interview on 01/30/13 at 4:25 PM, Staff G, Training and Quality Systems Coordinator stated that the facility had a corrective action tracking form that was in report format that the laboratory staff used for quality improvement, and the facility was considering using the same format for non-laboratory problems, but stated that she could not find any specific example of the form being used outside the laboratory.	L1171		
L1190	19 CSR 30-30.060(5) Complaints, Any person having a complaint Complaints. Any persons having a complaint	L1190		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

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REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L1190	Continued From page 11 pertaining to the care of a patient rendered by an abortion facility shall direct the complaint in writing to the Missouri Department of Health, Bureau of Hospital Licensing and Certification, P.O. Box 570, Jefferson City, MO 65102. The person making the complaint shall be contacted by the Department of Health within five (5) working days of receipt of the complaint and the complaint shall be investigated by the Department of Health within twenty (20) working days of receipt of the complaint. This regulation is not met as evidenced by: Based on interview, policy review, and review of the facility's patient rights document, the facility failed to provide accurate written notice of patient rights to inform patients or their representatives of their options of who to contact to file a grievance/complaint as required. The Ambulatory Surgical Center does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of the facility's policy titled, "Client Services", revised 12/12/12 stated: -A bill of rights is available, either framed and hanging on the wall, or on the clipboards; -This specified client's rights and the facility's obligations; -For any concerns, it gives a managerial contact for clients to call; -Clients with grievances will be given to the supervisor or manager on duty; -Should this person not be available or be unable to resolve the client's issue, the client will be offered the option to talk with the next managerial level, and; -They can do this by calling that person's number	L1190		

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	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

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REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L1190	Continued From page 12 and extension directly or staff can take the client's name and number and forward it. 2. Review of the facility's "Bill of Rights" that patients are given prior to a procedure, gave direction for the patient to contact the Health Center Coordinator or the Director of Surgical Services, and provided the facility telephone number. (Note that the notice of rights failed to state that patients could report their complaint to the state agency, failed to include the state agency address, and telephone number). 3. During an interview on 01/31/13 at 11:00 AM, Staff A, Vice President of Patient Services stated that the facility had not been including/providing the state agency information (address and telephone number) in the "Bill of Rights" document that was presented to patients.	L1190		
L1252	19 CSR 30-30.070(3)(L) At least two (2) ABC-type fire extinguishers At least two (2) ABC-type fire extinguishers shall be located in the facility, one (1) in the clinical area; This regulation is not met as evidenced by: Based on observation and interview, the facility failed to conduct a monthly inspection of the portable fire extinguishers. This deficient practice affects all occupants in the facility. The facility does an average of 340cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. Observation during a tour of the facility	L1252		

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	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1252	Continued From page 13 conducted on the morning of 01/30/13, showed the monthly inspection tags on all of the portable fire extinguishers were blank indicating a monthly inspection had not been conducted. 2. During an interview on 01/30/13 at 2:20 PM, Staff A, Director of Patient Services stated the facility staff did not conduct monthly inspections of the portable fire extinguishers.	L1252		

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	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced allegation survey was conducted at this facility from 01/30/13 - 01/31/13. Complaint MO00082879. A state licensure inspection was conducted in conjunction with the allegation survey. The complaint (MO00082879) was found to be unsubstantiated. Deficiencies as a result of the licensing inspection are as follows:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on employee personnel file review, and review of the state statute, the facility failed to perform periodic Employee Disqualification List (EDL) checks on three of three employee personnel files reviewed. The facility does an average of 340 cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. EDL checking requirements are as follows: Section 660.315, RSMo Entities required to check the EDL: 1. Licensed as operator under Chapter 198; 2. Provides in-home services under contract with the department; 3. Temporary nurse staffing agencies;	L1111		

	STATE OF MISSOURI PLAN OF CORRECTION	
Provider/Supplier Name:	Reproductive Health Services / Planned Parenthood St. Louis Region & SW MO	Survey Date
STREET ADDRESS, CITY, ZIP:	4251 Forest Park Ave, St. Louis MO 63108	1/30 - 1/31/13
	(X1) PROVIDER/SUPPLIER/CLIA INDENTIFICATION NUMBER 17-	26D0438374

The Administrator signing and dating the first page of the CMS-2567/State Form is indicating their approval of the plan of correction being submitted on this form.

(X4) ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
L1111	A new human resource policy has been initiated to ensure that all RHS staff, prior to hiring, will be checked through the EDL data base. RHS of PPSLR will not hire a person on this list. In addition the existing, current staff will be checked against the EDL. (RHS of PPSLR has already registered under the MO State Dept of SS and is awaiting and log ins)	
	Attached: New Policy	
	Person Responsible: VP of Human Resources	3.15.13
	Monitoring and Incorporation into QAPI process: a report of activity will be forwarded to VP of Patient Services for incorporation into meeting minutes	Starting w/April '13 meeting
L1128	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure single use medications are discarded after use on each patient	
	Attached: New Policy, Page 7	
	Person Responsible: VP of Patient Services	2.27.13
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff.	2.27.13
	Person Responsible: Director of Surgical Services, Clinical Manager	
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator will spot check this weekly for the first month and then monthly. A consolidated report on all Infection Control activities will be shared with the VP of Pt Services and at the CQA meeting	First checks wk of 3/4 and continuing
	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure the multi-dose vials are appropriately dated when they are opened	2.27.13
	Attached: New Policy, Page 7	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	2.27.13
	Person Responsible: Director of Surgical Services, Clinical Manager	

David L. Eisenberg, MD, MPH

Medical Director
Title

2-27-13
Date

	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator will spot check this weekly for the first month and then monthly. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the CQA meeting	First checks wk of 3/4 and continuing
	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure that expired medications are not available for patient use. The revision clarifies dates on which supplies are checked (i.e. the first working clinic session of every month).	2.27.13
	Person Responsible: VP of Patient Services	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	
	Attached: policy, page 3	
	Person Responsible: Director of Surgical Services, Clinical Manager	2.27.13
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator or a delegate from the infection control committee will spot check this weekly for the first month and then monthly. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the CQA meeting	first full week of every month
	The General Standards section of the policy and procedure manual has been revised to ensure that expired items are not available for patient use. The policy is more specific on when items are checked and how discarded	2.27.13
	Person Responsible: VP of Patient Services	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	2.27.13
	Attached: new policy, pages 26 and 27	
	Person Responsible: Director of Surgical Services, Clinical Manager	
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator or a delegate of the Infection Control Committee will check this in the first week of the month. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the quarterly CQA meeting.	first full week of every month
	To ensure that a sanitary environment is preserved several actions have been taken and are to be taken:	
	1) new footstools have been purchased and the old discarded	2.15.13
	2) bids have been sought for new berkeleys and new IV poles	2.13 & 2.25.13
	3) the maintenance and cleaning crews are using cleaning products to determine if our surfaces are easily cleanable or need replacing	2.13 - 2.28.13
	4) for items that must be purchased, this will occur	3.15.13
	Person Responsible: VP of Patient Services and VP of Finance/Operations	
	5) ongoing monitoring of equipment, cleanable surfaces, and their condition	
	Person Responsible: procedure room staff and Infection Control Committee	
	Staff Training: Training and Quality Systems Coordinator and Clinical Manager	3.1.13

	Monitoring: ongoing monthly auditing and checking of equipment and cleanable surfaces. Recommendations for improvements to VP team as indicated. Audits will be shared at CQA quarterly meetings	Monthly starting in March '13. Reports quarterly
	To ensure the facility is free of dust/debris throughout the medical area, including procedure rooms, storage and supply room:	
	1) the air ducts in the procedure rooms and recovery have been cleaned	2.5.13
	2) the maintenance dept will check them monthly and clean them as necessary	3.5.13 ongoing
	3) a new cleaning schedule has been put into effect - procedure room and utility staff clean their rooms every Tuesday prior to the start of clinic	2.15.13
	4) the cleaning staff will provide heavy cleaning of the entire clinical area every Monday and Thursday	
	5) Medical Assistants will rotate responsibility for storage and shared areas	
	6) a check list is being designed to ensure all items are addressed	2.27.13
	Staff Responsible for Cleaning: Medical Assistants and Housekeeping	
	Staff Responsible for Monitoring: Management (rotating) and Infection Control Committee	
	Timeline for monitoring: weekly checks for first month, then monthly	Tuesdays
	The Infection Control Committee, which was founded in November 2012, invited staff members to join and will be responsible for: updating the manual, designing audits, monitoring outcomes, recommending training, setting standards, ensuring incorporation of changes into QAPI, and reporting to the Clinical Quality Assurance Committee. All of the above will be monitored by them as well as by those stated above.	first meeting week of 3/4/13
	Staff Responsible: Training and Quality Systems Coordinator as manager of the committee	
	Staff Training: For above issues, already stated. For new topics, training will be as indicated and decided upon by committee	
	Monitoring and incorporation into QAPI process: reports to the Clinical Quality Assurance Committee and Medical Director	quarterly reports
L1170	The Quality Assurance Program will be improved via the following actions:	
	1) the agenda will be more specific regarding all of the issues identified by regulations	2.6.13
	2) the review of patient records will include a new log of all cases in which gestational age is 18 weeks or greater and will show a review by a physician (i.e. the Medical Director)	3.1.13
L1171	3) the notes will identify each problem and the accompanying action to be taken to resolve the problem	2.6.13
	4) successive notes will address the action taken and the outcome	Next QA meeting in April 2013
	5) further action will then be addressed as indicated	

	Staff Responsible: VP of Patient Services, Medical Director, and Training and Quality Systems Coordinator	
	Committee Training and Preparedness: was discussed at the 2.6.13 meeting. Follow up with individual members week of 2.25.13 to ensure actions as decided	
L1190	The patient Bill of Rights has been updated with the addition of the address and phone number of the MO Department of Health and Senior Services, Bureau of Ambulatory Care. It is made assessible to patients by being attached clipboards that are given to every patient with their initial paperwork.	2.1.13
	Attached: new bill of rights	
	Staff Responsible: VP of Patient Services	
L1252	PPSLRSWMO pays to have annual inspections of the fire extinguishers. In addition, the maintenance staff will now do a monthly inspection of the fire extinguishers to ensure the pressure is correct, they are in working condition, and there is no blockage.	first week of March 3/4/13
	Staff Responsible: Maintenance	
	Training: none required	
	Monitoring to ensure POA is effective: will be checked for three months by VP of Finance/Operations and then spot checked over the next year	once in March, April, May, then periodically

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CLINICAL PROGRAM STRUCTURE
GENERAL STANDARDS
PAGE 26 AND 27
(entire document not sent)

VIII. MEDICAL EQUIPMENT AND SUPPLIES

Medical Equipment and Supplies must —

A. Be appropriate and adequate to provide the services offered. All centers have microscopes, refrigerators, autoclaves, venipuncture and injection supplies, scales, sphygmomanometer, and appropriate gynecologic equipment.

B. Equipment is checked and calibrated annually by a contract service for safety, and written documentation is kept on file at the administrative office.

L1128

A. Equipment is also checked by staff and managers monthly according to the infection control policy

- **a. Check for rust, cleanliness, tape, or any uncleanable surface**
- **b. Worn or defective equipment must be reported to the manager for replacement or fixing by the staff who identified this**

D. Supplies are checked regularly and at least monthly by the assigned staff. The person checking will vary per center and is delegated by the manager of the center.

a. For RHS, staff are the medical assistants assigned to procedure rooms and to storage areas

b. For RHS, the LPN/RN will check the recovery and storage there

c. For HCs, the support staff (MA / Patient Educator) will check the exam rooms, labs, storage area

d. Supplies are rotated to ensure oldest used first

e. Expired supplies must be removed from the active stock and not used for patient care

f. Supplies are checked on the first clinic day of each month

g. Managers and the Infection Control Committee will be providing spot checks periodically

E. See specific sections for additional supply and equipment for that service.

F. Facility Cleaning Standard
As a medical facility, PPSLR/SWMO must maintain sanitary environments for patient

Care. To ensure this:

- **a. Some centers have a contractual agreement with a cleaning service that does heavier cleaning 3 x weekly**
- **b. In the interim between their visits, staff are**

responsible to empty trash, wipe down any spills, disinfect areas that have become contaminated or dirty

c. **Some centers have their own cleaning crew who may perform the heavier cleaning of mopping, baseboards, vacuuming, etc – this must be done according to volume of traffic and may be 2 – 3 times weekly**
d. **At RHS, the procedure rooms, recovery, and storage are closely monitored and cleaned at least once per week – every Monday for the heavier cleaning and every Tuesday before clinic session for dusting and debris management**
e. **The monthly Infection Control audit will check that a sanitary environment has been achieved for patient care**

For additional information, please see the Infection Control Manual and audits

IX. INFECTION PREVENTION/CONTROL

All affiliates **must** have an infection prevention program in place. The ARMS *Infection Prevention Manual* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs. .

PPSLR/SWMO manual uses the ARMS one as the basis and provides both policy and procedural information. An Infection Prevention Committee has been established through the Patient Services Department and consists of nursing, administrative, and clinical support staff. Their purpose is surveillance, investigation, control and prevention of infection. This will be accomplished by review, revision, and approval of infection prevention policy and procedures.

X. RISK AND QUALITY MANAGEMENT

L1170 and L1171

PPSLR/SWMO and its affiliate RHS of PPSLR/SWMO have a structured and permanent Risk and Quality Management Program in place. The ARMS *manual Risk Management: The Path to Patient Safety* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs. The affiliate's Quality Management Program includes the following:

1) A CQRM Committee chaired by the Training and Quality System Coordinator and membership of: CEO; VPs from all departments (Patient Services; Political; Education and Diversity; Administration and HR; Finance and Operations; Development), Medical Director, and Board member.
Committee is responsible for agency oversight for QM/RM activities and concerns such as security, technology, personnel issues. The committee is responsible for overseeing goals and identifying processes to evaluate. This is accomplished by the following:

- Review of reporting agency departmental and committee audit findings to identify and explore possible risk and exposure areas
- Develop protocols/procedures as needed to reduce the risk of exposure to loss

- Inclusion of risk management concepts in the annual Quality Management Plan
- Participate in the annual review of the PPFA QM & RM Self-Assessment Survey Review to ensure PPSLR in compliance with standards and guidelines for accrediting agencies such as Planned Parenthood Federation of America, Title X and Medicaid
- Committee members serve in an over-sight capacity for monitoring and improving PPSLR/SWMO facility management in the areas of safety and security for clients, visitors, staff and volunteers

Page 29 addition regarding CQAC

The following agency committees report to the QM committee:
Clinical Quality Assurance Committee for Patient Services (all divisions)

Due to state licensing, the CQAC must address the following issues – this will be done through a detailed agenda, discussion, notes, and analysis of the outcomes of the decided upon actions.

From state regulations:
(J) Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following:

1. ***Completeness of clinical records;***
2. ***Incidence of morbidity and mortality;***
3. ***Intraoperative and postoperative complications;***
4. ***All cases transferred to a hospital'***
5. ***All cases that resulted in a length of stay of more than twelve (12) hours;***
6. ***Errors in diagnosis;***
7. ***Problems in compliance with state and local laws and regulations;***
8. ***All cases in which the gestational age was determined to be beyond eighteen (18) weeks.***

(K) The quality assurance program must show evidence of action taken as a result of the identification of the problems.

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L1128

Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri

Infection Prevention Compliance Audit
Sterilization Practices

	Met	Unmet	Improvement Plan/Date to be Completed
1 All medical equipment (i.e. speculums, medical instruments, etc.) are immediately placed in appropriate disinfectant solution after use			
2 Staff can verbalize above disinfectant solution ratio			
3 Proper PPE is worn by staff during cleaning process (utility gloves with instrument cleaning in utility)			
4 Instruments are not allowed to dry before cleaning procedure			
5 Documentation exists for high level solution check for each use			
6 Equipment sterilized in the autoclave contains an indicator for sterilization within each package			
7 No package wrapped for steam sterilization is more than 12x20x12 inches in size			
8 Documentation of weekly steam sterilizer cleaning and spore testing			
9 Supplies of sterile instruments are stored no less than 8-10 inches from the floor and 18-20 inches from the ceiling			
10 Sterile supplies are checked monthly for integrity of the pack			
11 All sterile items are labeled with the date of sterilization and specific autoclave			
12 No expired merchandise or supplies on shelves in active stock			
13 Multi-use vials dated & initialed when opened and discarded according to regulations			
14 Single use medications are used for one patient and discarded after use			
15 All exam tables are wiped with disinfectant after each procedure			
16 Sterilize and non-sterile items are stored separately			
17 All equipment is sterilized in "open" position			
18 Sterile supplies are rotated to ensure use of most recently sterilized equipment last			
19 Antimicrobial hand rinse available			
20 No biohazard in white bag trash			
21 Sharp containers easily accessible (in lab, exam, utility, procedure and recovery areas)			
22 PPE available (masks, protective eyewear, utility gloves, plastic apron, etc)			
23 Vaginal probes are disinfected between each patient			
24 Condoms are used to cover vaginal ultrasound probe			
25 Tubing labeled by manufacturer as single use tubing is disposed of infectious waste after a single use.			
26 Multi-use suction tubing is cleaned, then disinfected as for a semi-critical item			
27 Abortion procedure bottles are changed, cleaned and disinfected between patients			
28 MVA is completely disassembled, cleaned and receive high-level disinfection			
29 If Cidex used, must be checked and documented on day of use to ensure effectiveness			
30 MSDS log current with supplies used in surgical center			

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Auditor Name:_____Title_____ Date_____

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L1128

Signature & Title of reviewer:_____

Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri

Infection Prevention Compliance Audit
Standard Precautions, Hand Hygiene and PPE

	Met	Unmet	Improvement Plan/Date to be Completed
1 Sharp containers are leak proof, puncture resistant, labeled with biohazard label, sealed and disposed of when they are no more than ¾ full and sealed completely before disposal			
2 All sharps are disposed of in designated sharps containers (include hypodermic, intravenous or other medical needles, syringes with an attached needle or other sharps, scalpel blades, blood vials, slides & cover slips, syringes that have come in contact with blood or infectious agents, etc.)			
3 Employees demonstrate proper hand washing or disinfecting technique before putting gloves on /removal of gloves and before each patient encounter.			
4 Eye protection/face shields are used when activity holds possibility of splash			
5 Safety needles are used when available; includes needle devices containing built-in safety features			
6 When sterile gloves are used, proper technique is followed for putting on and removal			
7 Appropriate PPE (i.e. various gloves, masks, face shield, lab coats, CPR shield) is readily available in each area of health center (lab, procedure, utility rooms, etc)			
8 Gloves are worn by staff when contact with blood, OPIM, mucous membranes and non-intact skin may occur			
9 Gloves are worn when giving injections, drawing blood and performing Venipuncture			
10 Red bags are used for non-sharps, regulated medical waste (i.e. products of blood & anything caked, soaked or dripping with blood; saturated materials containing blood)			
10 PPE is disposed of in proper container (red bags if contaminated)			
11 Every hand washing station contains soap, hand disinfectant and towels available for proper hand hygiene			
12 Surgical scrub is employed for hand hygiene by physician/clinician before clinic surgical session and waterless alcohol foam product used between patients			
13 Sterile packages are used that have outside tape that indicates the package has been processed			
14 Non-sterile persons avoid reaching over a sterile field; sterile persons avoid leaning over a non-sterile area			
15 When sterile packs are opened, the outside of the package never touches the inside			
16 Routine schedule and guidelines for housekeeping & cleaning is followed			
17 Patient care equipment is free from dust and debris in procedure, storage and supply areas			
18 Environmental surfaces are thoroughly cleaned/disinfected in patient care areas between patients			
19 Staff can verbalize guidelines for cleaning/disinfecting after a blood/body fluid spill			
20 Emergency Surgical Cart free from dust & debris			

L1128

Auditor Name:_____ Title:_____ Date:_____

Signature &Title of reviewer:_____

Americans United for Life

L1128

Staff Training
2.27.13

Trainers:
Lead Clinician Susan Bender, NP
Director of Surgical Services Celeste Smith, LCSW

I. Time for a change
   a. What are some things you think we need to change?
   b. What gets in the way of us being excellent?
   c. What can we start doing differently?
II. Single Use Medication Vials for One Patient
III. Multi-Dose Medication Containers are Labeled with Date Opened
IV. Labeling Pre-Drawn Medications
   a. Date
   b. Time
   c. Initials of Staff Drawing Up Meds
V. Expired Medications
   a. Plan to check the last working day of each month
VI. Expired Supplies
   a. Plan to check the last working day of each month
VII. Clean and Sanitary Environment
   a. Environment Includes
      i. Dressing Room
      ii. Recovery Room
      iii. Procedure Rooms
      iv. Utility
      v. Supply Areas
      vi. Storage Areas
      vii. Hallways
      viii. Floors
      ix. Ceilings
   b. Targeted clean each Monday/Tuesday Morning
      i. Dust
      ii. Debris
      iii. Clutter
      iv. Appearance Matters
      v. Day to Day Upkeep
      vi. Leave your workstation clean
   c. Un-cleanable Surfaces
      i. What are they?
      ii. How do we fix them?
      iii. How do Monitoring them?
VIII. Infection Prevention Committee
   a. What is it?
   b. Who is on it?
   c. How can it help us?
IX. Questions?

Americans United for Life

AS A PATIENT OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION AND SOUTHWEST MISSOURI, YOU HAVE THE FOLLOWING RIGHTS:

The RIGHT to no discrimination regardless of race, color, national origin, disability, age, ethnicity, sexual orientation, financial ability, education level, marital status, religion, number of pregnancies, method of referral, contraceptive preference or other factor;

The RIGHT to be treated with dignity and respect without harassment;

The RIGHT to decide whether or not to bear children and if so, to determine the timing and spacing;

The RIGHT to privacy and confidentiality in all aspects of the service we provide;

The RIGHT to know of the effectiveness, possible side effects, and complications of all contraceptives;

The RIGHT to participate in selecting the contraceptive methods to be used;

The RIGHT to know the results and the meaning of all tests and examinations;

The RIGHT to access your records and have them explained;

The RIGHT to know the meaning and implication of all forms we ask you to sign;

The RIGHT to consent to or refuse any contraceptive method, test, examination or treatment;

The RIGHT to an explanation of fees and services before services are provided.

- You will not be denied access to services if unable to pay
- We accept Medicaid and Medicare
- We accept commercial health insurance
- Please discuss any special concerns with our staff

If any problems should arise during your visit, please ask to speak to the Health Center Coordinator or contact the Director of Surgical Services at 314-531-7526 ext. 231.

Planned Parenthood

Americans United for Life

You may also contact the State of Missouri Department of Health and Senior Services, Bureau of Ambulatory Care. PO Box 570, Jefferson City, MO 65102. Telephone: 573 751-6083.

L1111

BACKGROUND CHECKS AND INVESTIGATIONS POLICY

PPSLRSWMO recognizes the importance of maintaining a safe and productive workplace with honest, trustworthy, qualified, reliable and non-violent employees. For the benefit of all employees and PPSLRSWMO, in furthering these interests and enforcing PPSLRSWMO policies, PPSLRSWMO **will** perform, or request that third parties perform, "background checks" or other types of investigations. These background checks and investigations may be performed by PPSLRSWMO at its discretion. **The Vice President of Human Resources will be responsible for performing all "background checks" that are applicable under Federal, State and Planned Parenthood of America (PPFA) laws and requirements.**

Background checks and investigations performed for PPSLRSWMO may include the use of consumer reporting agencies which may gather and report information to PPSLRSWMO in the form of consumer or investigative consumer reports. Such reports, if obtained, may contain, but are not limited to, information concerning an applicant's or employee's credit standing or worthiness, credit capacity, character or general reputation. The types of reports that may be requested from consumer reporting agencies under this policy include, but are not limited to, credit reports, criminal records checks, driving records, and/or summaries of educational and employment records and histories. The information contained in these reports may be obtained by a consumer reporting agency from private or public records sources or through personal interviews with an employee's co-workers, neighbors, friends, associates, current or former employers or other personal acquaintances.

Pursuant to this policy, PPSLRSWMO may request consumer reports, including records checks and investigative reports based on interviews, in connection with an individual's application for employment, or at any time during the course of an employee's employment with PPSLRSWMO, for purposes of evaluating their suitability for employment, promotion, reassignment or retention as an employee.

All PPSLRSWMO Reproductive Health Services (RHS) candidates prior to hire will have a criminal background check and Employee Disqualification List (EDL) search completed prior to hire per the Missouri Revised Statutes Chapter 660 section 317.

Employees are expected to cooperate fully with the background checks and investigations policy. Such cooperation includes, among other things, providing truthful and complete information in response to inquiries made by PPSLRSWMO or third party investigations during the course of investigations and providing appropriate written authorizations that may be required by law so that

PPSLRSWMO may obtain complete investigation reports. Failure to cooperate in these checks or investigations, or any attempt to interfere with PPSLRSWMO attempts to obtain information, may result in disciplinary action, up to, and including, termination.

Americans United for Life

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PHARMACEUTICAL SERVICES
See pages 3 and 7

I. PHARMACEUTICAL SERVICES

Affiliate Staff

1. **Medical Director** — is responsible for developing policies and procedures for pharmaceuticals that **must** include
   - formulary of all drugs stocked in the affiliate that is reviewed annually
     i. Consider the potential for medication errors when developing formulary. Look-alike, sound-alike drugs should be identified as being at "high risk" for potential error. Extra steps should be taken to ensure safety.
   - list of additional therapeutic/pharmacologic classifications of drugs that may be ordered for clients to obtain at outside pharmacies
     - The formulary is approved annually with medical protocol updates
     - All drugs, devices, and medications stocked in the affiliate are approved by the Medical Director in advance of purchasing / acquiring and providing.
     - The Medical Director only approves drugs that are FDA approved and only from manufacturers certified by the FDA, unless the medication is part of a research study.
     - All research study medications must be approved by the IRB and Medical Director prior to use.
     - PPSLR has both an internal (for items stocked in-house) and external formulary (inclusive of in-house and by written/e-prescription).
     - RHS has a formulary specific to abortion care approved by the Medical Director.
     - The Medical Director, Lead Clinician, and VP of Patient Services review the formularies at least annually. The Medical Director approves and signs off on the formulary of both departments.
     - RHS has a formulary. The surgical physicians have discretion to provide other medications as needed.
   - provision of pharmaceuticals in accordance with all state/local laws and regulations
     - PPSLR/SWMO and RHS of PPSLR/SWMO pharmaceuticals are provided by physicians, by clinicians or by physician designee.
     - APNs work under collaborative practice agreements with the PPSLR Medical Director and Associate Medical Directors. They have prescriptive and dispensing privileges.
     - RNs/LPNs work under standing orders with the PPSLR Medical Director.
     - Physicians have the ability to prescribe as indicated for patient care.
   - a drug control system that covers the interval from the time pharmaceuticals are ordered until they are provided to the client
     - PPSLR/SWMO's system includes the interval from issuing a request for order from health and surgical centers to the purchasing clerk, to ordering them from the pharmaceutical companies, to delivery and storage, to client provision.
   - inspection of all drug storage areas to remove expired drugs
   - designation of which staff may have access to bulk storage areas
   - management of pharmaceutical product irregularities and drug and device recalls
2. There **must** be documentation that in-service education pertaining to the nature

and safety aspects of pharmaceuticals is provided to staff involved in the preparation and provision of medications.

- PPSLR/SWMO provides an annual training for staff, primarily clinicians and licensed providers

FYI — Look-alike, Sound-alike (LASA) Medications

Confused drug names are one of the most common causes of medication error. With tens of thousands of drugs currently on the market, the potential for error due to confused drug names is significant and exists worldwide. Contributing to the risk of confusion are illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labeling, similar clinical use, similar strengths, dosage forms, frequency of administration, and the failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct rigorous risk assessments, both for nonproprietary and brand names, prior to approving new product names.

Go to the Institute of Safe Medication Practices for a list of LASA medications. The list includes those medications that are known to have been involved in medication errors, as well as the Joint Commission's list of LASAs.

(WHO 2007); (ISMP 2010)

Procurement

1. There **must** be a written order for all drugs/pharmaceuticals/chemicals brought into the affiliate.
   - A copy of the purchase order or the prescription **must** be kept in the affiliate's files. A signed receipt **must** be obtained for pharmaceuticals shipped from a central location to outlying centers or clinics. If the delivery is made by affiliate staff, a signed receipt is not necessary.
     - The original order is issued by the supervisory staff of the health center or surgical center;
     - The order is sent to the Payroll/Purchasing Clerk via internal e-mail or fax;
     - Each facility has its own account number with each supply or pharmaceutical company;
     - The order is placed by the purchasing clerk at the administrative office;
     - Most deliveries are sent directly to the service location from the company;
     - Specific items are shipped centrally to control pricing;
     - Upon delivery, products are checked for accuracy and security, the packing slip is dated and initialed;
     - A copy of the purchase order or the prescription is and must be kept in the affiliate's files.
     - For items shipped to a central location, supervisory staff is responsible for picking up the supplies and completing a form that is sent to purchasing detailing amount and to which budget to allocate costs.
     - Finance maintains all purchase orders, packing slips, invoices, and paid statements for all pharmaceuticals.
   - Controlled substance order and receipt records **must** be filed separately from

the other pharmaceutical purchase records. RHS is the only facility that orders controlled substances.

2. If pharmaceuticals are routinely purchased from a community or hospital pharmacy and if the items are not supplied in manufacturer original containers, there should be a written contract specifying, as a minimum, requirements for labeling. PPSLR/SWMO seldom, if ever, purchases, pharmaceuticals from other than manufacturers. An exception is the free meds provided by the states of MO and of IL for the IPP programs.
3. If available, pharmaceuticals should be purchased in manufacturer prepared unit-of-use packages.
    - An exception is limited STD medications provided free to the health centers from the Illinois Department of Health and the MO Department of Health and limited medications for RHS. In these cases repackaging standards in this section are followed.
4. Only drugs and devices approved by the Federal Food and Drug Administration (FDA), and manufactured for sale in the United States may be used. Affiliates may not import drugs and/or medical devices from other countries for use in their health centers.
5. For any additional drugs that must be prescribed and are not purchased, the "out-of-house" formulary is utilized.

Storage

1. Access to stored pharmaceuticals
    a. The bulk storage area **must** be secure. The clinician or nurse on duty has the key in her possession to enable easy provision to clients. Other staff may have access via the clinician. Limited supplies are accessible to clinic staff working the receptionist desks.
    b. Controlled substances **must** be under double lock and in a secure area at all times. RHS is the only facility with controlled substances and follows MO law regarding storage of the drugs.
    c. Access to pharmaceuticals dispensed from within client care areas should be limited to health care providers responsible for dispensing these items.

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2. **Pharmaceuticals in all storage areas**
    a. Arrange medications so that the oldest stock is used first
        i. On the first clinic session of each month, a delegated staff reviews the inventory to ensure that stock is being properly rotated and has not expired
        ii. Expired inventory must be removed from active stock and marked as expired to ensure it is not available to patient care. It will be returned or discarded according to the vendor or manufacturer's instruction.
        iii. The senior management team, during routine audits, will also check the inventory for proper stock rotation.
    b. Do not store look-alike, sound-alike medications alphabetically. Store them out of order or in a separate location (The Joint Commission 2001)
    c. Pharmaceuticals meant for internal use **must** be stored separately (i.e. on a separate shelf) from those for external (i.e. topical) use only. Clear and highly visible labeling is required.
3. Other PPSLR/SWMO policies related to storage
    a. Inventory levels for pharmaceuticals that are not high volume should not exceed six-month stock.
    b. All pharmaceuticals, contraceptives, and therapeutics will be stored

according to the manufacturers' suggestions to ensure preservation (i.e. refrigeration, limited access to light exposure, etc).

c. An inventory check is performed monthly by supervisory staff to ensure accurate counts and to limit misappropriated medications and supplies.
d. Expired pharmaceuticals should be disposed of by throwing them into the biohazard box, sending them back to manufacturer, or taking them to appropriate and identified pharmacies that PPSLR/SWMO has approved for disposal (see VP of Patient Services or Clinical Manager). (Varies with product) Some items may be used for demonstration and educational purposes. Expired items must be accounted for on the Monthly Inventory Form and deleted from the inventory as soon as discovered to be expired.
e. The supervisory staff of all centers is responsible for discarding pharmaceuticals appropriately. The Purchasing Clerk will contact the manufacturer to determine if a rebate on expired products exists.
f. For any centralized inventory the Purchasing Clerk will remove it from the shelves.
g. No client will be dispensed a drug with an expired date.
h. Controlled substances must be destroyed by two nurses and documented on the Controlled Substance Dispensing or Administration Log Sheet. (see below for more policies/procedures on controlled substances)

4. At the end of each fiscal year, a full manual inventory is performed in each site.

Repackaging — i.e., the preparation of multiple containers of dispensing size from a bulk container (for example, repackaging a bottle of 1000 tetracycline tablets into vials of 20 tablets each). Repackaged vials are stored and dispensed to clients as needed.

1. Repackaging **must** be done in accordance with state/local laws/regulations. For PPSLR/SWMO and affiliates this is under the supervision of a physician who is on the premises at the time of repackaging.

2. A log **must** be maintained to document the supervision (by signature), the person doing the repackaging (by signature) and the identification of the bulk drug being repackaged. Logs **must** be archived according to state/local laws/regulations. The log should contain the following information:
   - complete product description — name, strength, manufacturer
   - the manufacturer's lot number
   - an expiration date, no later than the manufacturer's expiration date of a not previously opened manufacturer's container.
   - a control number or some other unique (code) identification that will link that manufacturer and drug lot with the repackaged units

3. All repackaged units **must** have a standard label affixed to each package (bottle, etc.) before they are entered into active stock. The label **must** include at least the following:
   - name and address of the affiliate
   - name of the drug and quantity
   - strength of the drug when appropriate
   - The expiration date, for drugs repackaged in "tight" containers such as plastic vials or glass bottles.
     - This should be the date specified on the original manufacturer's container, or one year from the date the product was repackaged, whichever is earlier.
     - The expiration date for drugs that are repackaged from unit dose

containers should be no greater than 60 days from the date of repackaging, or the manufacturer's expiration date on the original container, whichever is earlier.
  - State laws may be applicable to expiration date for repackaged pharmaceuticals.
- the control number linking that unit with the manufacturer's product drug lot — for example, a code showing the month and day of repackaging and number repackaged that day (as below, where 01=month, 21=day of repackaging, and 04=fourth item repackaged that day)

Sample label for drugs repackaged in tight containers:

Planned Parenthood of St. Louis Region 888 Main St., City, State, ZIP
Acetaminophen Tablets 325 mg, Qty. 25 Exp. 12/81, Control #012104

4. Safety precautions should be taken to indicate if the original repackaging unit has been opened prior to this dispensing, e.g., such as putting latex seals over the cap of the original vial after carrying out repackaging. An "x" could also be marked on the bottle cap or label to indicate it has been opened.

Compounding
PPSLR is not involved in the compounding of any medications in any of its facilities.

Labeling Prescription Vials for Clients
1. Prescription labels should be designed to enhance client safety. Click here (http://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp) to access recommendations from the Institute for Safe Medication Practices.
2. All prescription vials **must** have a permanently adhering label affixed directly to the container with at least the following information (currently provided by wholesaler):
   - name and address of the affiliate — The acronym, PPSLR/SWMO, may be used
   - name, strength, quantity dispensed of the drug
   - expiration date
   - lot number

   The label **must** also include the following information, which may be added by hand at the time of dispensing
   - date of the prescription
   - name of the client
   - directions for use including frequency and route of administration
   - name of the prescriber
   - number of refills, if applicable

   Sample label for prescription vial for client

Planned Parenthood of the St. Louis Region 888 Main St., City, State, ZIP
{date}

{client name} Take ____ tablets every ____ hours as needed for pain. {Dr. _____}
Acetaminophen Tablets 325 mg, Qty. 25 # refills Exp. 12/81, Control #012104

3. Auxiliary labels should be used to provide other information to the client, such as, "Do not drink alcohol." in the case of metronidazole. The label(s) that should appear on the prescription container can be found in the literature about each drug including the manufacturer's package insert. The labels come with the medications from the supplier and should be attached to the vial upon dispensing. PPSLR/SWMO standardizes the use of auxillary labels for consistency.

4. The plastic case or other container for oral contraceptives **must** bear the full label and include the FDA package insert. The refill units given at the same time need not be individually labeled. If the original case or container is not presented for subsequent refills, then the refill units can be put into a bag and the outside of the bag labeled.

Containers

1. Coin envelopes **must not** be used to dispense solid dose pharmaceuticals, since these do not meet the requirements of the Poison Prevention Packaging Act, a 1970 amendment to the Federal Food, Drug and Cosmetic Act requiring child-proof containers for pharmaceuticals. Self-contained packages, such as oral contraceptives or intravaginal creams, are exempted. PPSLR/SWMO does not use coin envelopes for any purpose.

2. All prescription medications should be stored in containers that protect them from light.

Controlled Substances

1. All controlled substances dispensed for out-patient use **must** bear the federally mandated auxiliary label: "Caution. Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

2. A daily count at the beginning and at the end of the clinic day **must** be taken on days when controlled substances are administered or prescribed. Discrepancies **must** be immediately reported to the supervisor, and recorded in the controlled substances inventory:
   - two countersignatures are required at the time of the count
     or
   - one person signing the daily count, and two persons taking and signing a full count every thirty days
     or
   - as required by state law
     1. RHS has two nurses (LPNs or RNs) doing the count
     2. Staff record on the Controlled Substance Dispensing or Administration Log: date of count, lot number of drug, first initial, last name and title of counting nurses.
     3. If the nurses who count recognize that the levels of the medication have fallen below the designated levels, they will notify the supervisory for reordering.

a. Fentanyl: ordered when it falls to 6 vials
b. Versed: ordered when it falls to 40 vials
c. Diazepam: ordered when it falls to 400

4. Approximately one month's supply of controlled substances will be kept in stock at all times to prevent the clinic from running out of stock. In cases where a national shortage is expected, more inventory will be approved by the manager

3. All inventory and purchase records for controlled substances **must** remain on file for the duration specified in state law if greater than the federal standard of five years. PPSLR/SWMO and its affiliate RHS maintains them for a minimum of seven years.

4. All Level IV controlled substances must be ordered and signed by the Vice President of Patient Services or the Clinical Manager (an APRN).

Other

L1128

1. **Single use medications are used for one client only and are discarded after use on each patient.**
   a. **Staff must follow manufacturer's labeling on how to use the medication**
   b. **The medication is discarded according to the manufacturer**
2. **Manufacturers' recommendations for storage of opened and unopened multi-dose vials must be followed.**
   a. **When a multi-dose vial is used, appropriate infection prevention procedures to prevent contamination should be employed. (CDC 2011)**
   b. **Vials must be discarded if there is evidence of contamination.**
   c. **If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial must be dated and discarded in accordance with manufacturer's instructions and state/local regulations**
      i. **If no specific guidelines are provided, CDC recommends discarding the vial within 28 days (CDC 2011)**
3. Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. (Note: Medication containers include syringes, medicine cups, and basins.) (The Joint Commission 2010)
4. **Syringes taken from a multi-dose vials must be labeled with date, time, and staff initials. If not used within 24 hours, it must be discarded no later than 24 hours.**
5. All clients receiving medications also **must** receive written or verbal instructions including the name, purpose and appropriate administration technique for each drug.
6. Patient package inserts **must** be available for IUCs, hormonal contraceptives, and other estrogenic and progestational substances.
7. Patient drug information should be provided on all other drugs dispensed.
8. The nature of the client education provided should be documented in the medical record.

Planned Parenthood of the St. Louis Region and Southwest Missouri

Staff Inservice/Training/Meeting

Date 2/27/13 Topic Medical Staff Training

Presenter/Trainer Susan Bender, NP & Celeste Smith, LCSW

Time 9:45am -10:45 Site RHS (Attach agenda and handouts)

Print Name	Signature & Title	Site
1 Carla Garner		RHS
2 Elaine Dostal		RHS
3 Stacey Honea		RHS
4 Elaine Lemus	Elaine Lemus	RHS
5 Kimberly Jones	Kimberly Jones RN	RHS
6 Alicia King		RHS
7 CALVIETTE (TISA) DUKES	Calvette Dukes	RHS.
8 S Bender	S Bender WHNP BC	RHS
9 Celeste Smith		RHS
10		
11		
12		
13		
14		
15		

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Planned Parenthood of the St. Louis Region and Southwest MO

Clinical Quality Assurance Meeting

Original Date: 1/30/13; Rescheduled Date: 2/6/13

Agenda

1) Review of Patient Care
    a. Intraoperative and Postoperative Complications and Occurrences — Sevic, Eisenberg
        i. Last Quarterly Report 2012
        ii. Annual Report 2012 (internal) and AIMS Report — Spencer
    b. Care by procedure / gestational age
        i. Medication
        ii. Surgical
            1. 17 weeks and under
            2. 18 weeks and over
    c. Identification of any problems
    d. Action plans

2) Transfers to Hospital — Eisenberg, Gianino, Kogut
    a. Administrative, Physician, Committee Review
    b. Security and HIPAA systems
    c. Identification of any problems
    d. Action plans

3) DOHSS Inspection — Management Team
    a. Results and findings
    b. Action Plan
    c. Ensuring full compliance with state/local laws and regulations

4) Accreditation — Spencer, Gianino
    a. Plans and Time lines to achieve full accreditation
    b. Agency Involvement

5) Audits — Bender, Moran, Spencer

6) Research Report — Eisenberg, Kogut

7) Old Business — All
    a. Follow up to any previously identified issues
        i. Continuing pregnancies
        ii. Consents
        iii. Next gen audits
        iv. Infection Control Committee

New Business and Announcements — All

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Planned Parenthood of the St. Louis Region and Southwest MO

Clinical Quality Assurance Meeting

Original Date: 1/30/13; Rescheduled Date: 2/6/13

Present: Eisenberg, D, Med Dir; Weisbart, E, Board; Gianino, P, CEO; Bender, S, Clinical Manager; Spencer, C, Training and Quality Systems; Moran, J, Dir HCs; Smith, C, Dir SS; Sevic, N, Data and Quality Compliance; Kogut, M, VP Pt Services

1) Review of Patient Care
    a. Intraoperative and Postoperative Complications and Occurrences — Sevic, Eisenberg
        i. Last Quarterly Report 2012
        ii. Annual Report 2012 (internal) and AIMS Report — Spencer
    b. Care by procedure / gestational age
        i. Medication
        ii. Surgical
            1. 17 weeks and under
            2. 18 weeks and over
    c. Identification of any problems
    d. Action plans

- Reports are attached
- All within expected standards of care
- Complication rates are low and within standard of care
- Patients both under and over 18 weeks of care have been managed well
- No specific identification of problems
- Action Plans: Medical Director requests comparison of current year to previous years for our trend in complications – Sevic to provide

2) Transfers to Hospital — Eisenberg, Gianino, Kogut
    a. Administrative, Physician, Committee Review
    b. Security and HIPAA systems
    c. Identification of any problems
    d. Action Plans

- In a three month period of time same number as in full 2011 year
- Upon analysis, appropriate transfers, patient care and decision-making was handled well, good patient care, no consistent theme or medical condition
- Reasonable decision making and time in center before transfer occurred
- Newest provider had 3 of the transfers – for new trainees this is expected, i.e. that transfers may be higher
- Analysis on three fronts:
    - CEO, VP of Pt Services, and Medical Director identified and discussed after the first 3 transfers. While not desired outcome, all fell within potentially expected outcomes

- Physicians – 3 primary attendings – and the administrative management team discussed 1/31/13 and came to same conclusion; recommendations for some limits on who we serve made and under discussion. Medical Director drawing up guidelines based on discussion
- CQ Committee 2/6/13 also looked at data

- Positive – we have greater continuity of care for patients due to our relationship with Wash U and the procedure of notifying the family planning fellow
- Action: Will update our ambulance transfer form to include: when called, when arrived, when pt discharged to EMS (and effective 2/18/13), when ambulance leaves the premises
- Action: CEO to contact BJC ED regarding potential for picketers and how handled
- Action: CEO to contact EMS for guidelines on the minimal information that must be shared with 911 calls to ensure safety and protect confidentiality
- Action: Staff to be retrained on making the calls after we get this information – Management team – ensure we identify if the call is urgent or emergent
- Action: CEO to work with operations regarding a way to limit the picketers from having full visual access to client as she is being transported – increase patient privacy

3) DOHSS Inspection — Management Team

a. Results and findings
b. Action Plan
c. Ensuring full compliance with state/local laws and regulations

- Surprise audit on 1/30 and 1/31 with 4 auditors
- Part of our licensing and partly due to concerted complaints
- Awaiting formal findings from state within 10 days of audit
- Will have 10 days to return our POA
- Summary of findings to committee:
  - Quality medical care with no indication of any violations of regulations
  - Some improvements on medication inventory; dust in select areas; updating some equipment; and increasing our infection control activities
- Committee was given the components that must make up the QA work
  - This agenda was changed to accommodate those issues
- Action Plan: management team to meet and agree upon immediate and long range procedures, training, changes to ensure improvements
- Action Plan: to respond to any cited deficiencies within 10 days of report

4) Accreditation — Spencer, Gianino

c. Plans and Time lines to achieve full accreditation
d. Agency Involvement

- Accreditation is Oct 9 – 11, 2013
- Plan is to send all documents by July 17, 2013
- Currently, all departments working on their EOPs
- Action: Patient Services, complete all manuals by April 30, 2013

Americans United for Life

5) Audits — Bender, Moran, Spencer

a. Vasectomy

i. Overall very good
ii. First full year at RHS – saw 63 men – a large increase over previous years
iii. One system issue – not enough follow up with patients to remind them of post op semen check
iv. Had turnover in the staff member who was handing this task – new person has been trained

b. Colpo and Pap Audits
   i. With new pap standards, many less colpos
   ii. Overall very good – a few issues that were resolved quickly
   iii. The colpo correlation log is / will be on line and reviewed by MDs
      1. Sign off 2 x per year
   iv. Lead NP able to audit via electronic record

c. Center audits
   i. With Next Gen, trying to audit different medical / clinical issues to ensure documentation
   ii. Action: Need to establish standards for what % of compliance is necessary per criteria
      1. Ex: consents would want to see 100%
      2. Patient Education forms could be lower
   iii. Action: Need to ensure NPs and support staff are clear on who doing what and limit redundancy
      1. Ongoing discussion – Dir of HCs and Clinical Manager with Training and Quality Systems will continue this
   iv. Recommendation: put them in "buckets" by priority / risk
      1. Must have for medical; or must have for financial
      2. Good to have

d. Infection control audits for HCs and RHS
   i. Quarterly audit listing both compliance and non- compliance areas
   ii. Overall good with some improvements noted
   iii. New Committee will address any new audit tools and how to improve outcomes

6) Research Report — Eisenberg, Kogut

a. Roche project is ending – enrollment has been completed; in final stages of the reviews/audits to ensure all paperwork
b. Snafu with consents that has been remedied.
   i. All were signed
   ii. Not all clients took one with them – our SOPs state they will be given one
   iii. Had to send all of those a certified copy
c. RLP
   i. Has begun at SG and CWE
   ii. Not yet enrolling enough patients – will be changing our use of staff to meet numbers
d. New industry sponsored one in discussion and analysis right now on the use of progestin contraceptives as quick start when mife is given
   i. Not yet approved and no budget yet

7) Old Business — All

a. Follow up to any previously identified issues
   i. Continuing pregnancies – No need to continue discussion - resolved
   ii. Consents – continue to track this and check for improvements
   iii. Next gen audits – continue to track this and decide on thresholds

iv. Infection Control Committee – continue to monitor the establishment of and the work of this group

8) New Business
   a. Worker's Comp Claims – up
      i. Few more splashes and sticks
      ii. Do not think it is a system problem – staff were counseled and systems analyzed
      iii. Some increase to our rates; Looking for new carrier as ours is getting out of the WC business

Submitted: Mary M Kogut, VP of Patient Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 1, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***PoC Approval***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Licensure & Complaint Survey conducted on ***January 31, 2013*** has been received in our office and forwarded to the surveyor(s). We want you to know the surveyor(s) has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 21, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Revisit Survey***

Dear Mary Kogut:

Please see attached results of the recent follow-up survey of ***March 19, 2013***. This relates to the Licensure & Complaint survey conducted ***January 31, 2013***. Your facility is now in compliance with Licensure requirements for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 03/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An onsite unnanounced revisit survey was conducted on 03/19/13. The facility was found to be in substantial compliance with the rules and regulations for Abortion Facilities found at 19 CSR 30-30.060.	{L 000}		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Acting Director

Jeremiah W. (Jay) Nixon
Governor

October 21, 2013

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00088230***

Dear Mary Kogut:

The results of the recent offsite complaint survey regarding your facility on ***September 19, 2013*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	09/19/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An off-site complaint investigation was conducted from 09/18/13 to 09/19/13. (Complaint MO00088230). The complaint was unsubstantiated. The facility was found to be in substantial compliance with CSR 30-20.060.	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 01/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An off-site complaint investigation was conducted from 10/22/13 - 01/06/14. (Complaint MO00089143). The complaint was unsubstantiated. The facility was found to be in substantial compliance with CSR 30-20.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

January 30, 2014

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

The results of the recent survey conducted at your facility on ***January 21, 2014*** indicate that your facility is in compliance with the Medicare regulations and State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	01/21/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An unannounced on-site state licensure survey was conducted at this facility on 01/21/14, in conjunction with an allegation survey for complaint #MO00089716. The complaint was unsubstantiated, and the facility was found to be in substantial compliance with CSR 30-20.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

August 5, 2014

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint MO00095990***

Dear Mary Kogut:

The results of the recent off site survey conducted on ***July 28, 2014*** indicate that your facility is in compliance with the State Licensure regulations CSR 30-20.060.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 07/28/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted for the purpose of review for 1 complaint in relation to the Missouri Regulations for Organization and Management for Abortion Facilities at CSR 30-20.060. The complaint is unsubstantiated with no deficiencies. #MO00095990- Unsubstantiated Reproductive Health Services has been found to be in substantial compliance with CSR 30-20.060	L 000		

Missouri Department of Health and Senior Services
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 14, 2015

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***March 31, 2015*** in connection with the ***State Licensure*** requirements and ***Medicare*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/31/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced, state licensure survey was conducted from 03/30/15 to 03/31/15. An onsite complaint investigation for complaint MO00100367 was also conducted and the complaint was found to be unsubstantiated. See below for findings related to the licensure survey:	L 000		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Restrict multi-dose vials to a centralized medication area separate from the patient treatment area; - Ensure expired medications were not available for patient use; - Have accessible and follow manufacturer's instructions for use; - Monitor the humidity in the clean and dirty instrument processing area; - Protect sterile items from dust and moisture by	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/31/2015

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L1128	Continued From page 1 placing a solid barrier on the bottom shelves; - Ensure staff wore personal protective equipment (PPE) appropriate to the task performed; - Replace worn or deteriorating patient-care items with functional, easily cleanable surfaces that would not harbor and transmit infections; and - Clean dirty/dusty surfaces. The Abortion Facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases. Findings included: 1. Review of the facility's, "Infection Prevention Manual," dated 09/09/13, showed the Infection Prevention Committee responsibilities and program components included: - Surveillance, investigation, control and prevention of infection; - Review, revision, and approval of infection prevention policies and procedures; - Take appropriate action to correct deficiencies relating to infection prevention as they are reported; - Use of standard precautions including Personal Protective Equipment (PPE); - Injection safety (i.e., if multi-dose vials will be used for more than one patient, the vials should be restricted to a centralized medication area); - Environmental cleaning; - Handling of contaminated furniture/equipment/linen/instruments/ supplies; - Medical equipment; and - Ongoing program evaluation of program. (Note: The facility's policy titled, "Pharmaceutical Services," dated 07/01/13, did not address that multi-dose medications should be restricted to a centralized medication area as shown in the facility's, Infection Prevention Manual .)	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1128	Continued From page 2 2. Review of the Centers for Disease Control and Prevention (CDC), document titled, "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care," dated 2014, showed to dedicate multi-dose vials to a single patient whenever possible. If multi-dose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment area (e.g., OR, patient room/cubicle). 3. Review of the facility's policy titled, "Pharmaceutical Services," dated 07/01/13, showed: - On the first clinic session of each month, a delegated staff reviews the inventory to ensure that stock is being properly rotated and has not expired. - Expired inventory must be removed from active stock and marked as expired to ensure it is not available to patient care. - Controlled substances must be destroyed by two nurses and documented on the Controlled Substance Dispensing or Administration Log Sheet. - A daily count at the beginning and at the end of the clinic day must be taken on days when controlled substances are administered or prescribed. - Syringes taken from multi-dose vials must be labeled with date, time, and staff initials. If not used within 24-hours, it must be discarded no later than 24-hours. - Manufacturer's recommendations for storage of opened and unopened multi-dose vials must be followed. (Note: The policy did not address that multi-dose medications should be restricted to a centralized medication area as shown in the facility's	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1128	Continued From page 3 Infection Prevention Manual.) 4. Observation of the pre-operative medication area on 03/30/15 at 2:15 PM showed: - An expired EpiPen ([brand] epinephrine autoinjector-medical device used to inject a measured dose or doses of epinephrine used for the treatment of allergic reaction), expiration 02/15. - A pre-drawn syringe labeled Fentanyl (narcotic pain medication) 50 micrograms, dated 03/28/15. Staff failed to dispose of the Fentanyl within 24-hours. - Staff failed to count the syringe of Fentanyl at the end of the day on 03/28/15. During an interview upon the observations, Staff C, Registered Nurse, Clinical Manager confirmed the EpiPen was expired. 5. Observation on 03/30/15 at 2:35 PM of procedure room #2 showed an opened, multi-dose vial of Lidocaine (numbing medication). 6. Observation on 03/30/15 at 2:40 PM of procedure room #3 showed an opened, multi-dose vial of Lidocaine. 7. Observation on 03/30/15 at 2:50 PM, of the clean side of the sterilization area showed two, Tuttnauer 3870-M autoclaves. Staff were unable to find the manufacturer's instructions for use (IFU). 8. Review of requested information on 03/31/15 at approximately 9:30 AM, showed the facility failed to provide the autoclave manufacturer's IFU. The information was requested again.	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/31/2015

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L1128	Continued From page 4 9. During an interview on 03/31/15 at 10:40 AM, Staff H, Health Center Assistant (HCA), explained the cleaning and sterilization process. She stated that she could not locate the autoclave manufacturer's IFU. 10. During an interview on 03/31/15 at 1:40 PM, Staff I, Practim Coordinator, stated they were still looking for the autoclave manufacturer's IFU. 11. During an interview on 03/31/15 at 1:45 PM, Staff J, Training and Quality Systems Coordinator, provided a copy of the autoclave manufacturer's IFU and stated they had just printed them off the Internet as they had not been able to locate the facility copy. 12. Review of the newly printed autoclave manufacturer's IFU showed: - Clean the door gasket daily; - Clean the autoclave airjet weekly; - Once every month, clean and check the safety valve; - Replace the door gasket every 12 months, or as needed; and - Once a year, inspect the locking device for excessive wear. Note: The facility failed to provide documentation they or the biomedical company performed these required services. 13. Review of a document provided by the facility titled, "PSS Biomedical Service," dated 08/07/14, showed documentation noting the manufacturer, model, and serial number for the autoclaves, but failed to document what service was provided. 14. Review of the CDC, "Guideline for Disinfection and Sterilization in Healthcare Facilities," dated 2008, showed:	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1128	Continued From page 5 - The American Institute of Architects 959 recommends the sterile storage area should be a limited access area with a controlled temperature (may be as high as 75° Fahrenheit (F) and relative humidity (30-60% in all work areas except sterile storage, where the relative humidity should not exceed 70%). 15. Review of the facility's document titled, "Affiliate Risk Management Services (ARMS) Infection Prevention Manual," (a corporate document) dated 2010 showed : - Guidelines for the storage of sterile supplies: *Store supplies 8 to 10 inches from the floor; and *Relative humidity must be controlled at 35-50%. 16. Review of the facility documentation log for the sterilization area showed staff failed to document the humidity levels of the clean and dirty side of the sterilization area. 17. Observation on 03/30/15 and 03/31/15 of the clean and dirty side of the sterilization area showed there was no humidistat to monitor the humidity level. 18. During an interview on 03/31/15 at approximately 10:30 AM, Staff H stated that they monitored the temperature but did not monitor the humidity. 19. Review of the American National Standards Institute (ANSI) and Association for the Advancement of Medical Instrumentation (AAMI) document titled, "ANSI/AAMI ST79:2010," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 09/24/10, showed:	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1128	Continued From page 6 - Sterile items should be stored in a manner that reduces the potential for contamination. - Shelving or carts used for sterile storage should be maintained in a clean and dry condition. - For sterile or clean supplies stored on the bottom shelf of an open-shelf (wire) cart, there should be a physical barrier between the shelf and traffic or housekeeping activities. 20. Observation on 03/31/15 at approximately 10:15 AM of the clean room showed a metal storage rack for sterile instrument sets. There was no protective barrier on the bottom shelf. (Note: There is a potential risk for splash onto the sterile items on the lower shelves without a barrier.) During an interview upon the observation, Staff H stated that they did not store instruments on the bottom shelf. 21. Review of the Occupational Health and Safety Administration standards titled, "Bloodborne Pathogens," dated 04/03/12, showed: - The employer shall ensure that the employee uses appropriate Personal Protective Equipment (PPE); and - Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. 22. Review of the facility's document titled, "ARMS Infection Prevention Manual," dated 2010 showed:	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L1128	Continued From page 7 - PPE is the clinic workers last line of defense against blood borne pathogens. PPE included face shields/masks, goggles, and safety glasses. - Masks, Eye Protection, Face Shields shall be worn whenever splashes, spray splatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated. Examples included washing soiled instruments. References for the document included CDC. 23. Review of the facility's documents titled, "Infection Prevention Compliance Audit," (tool) dated 01/09/14, showed staff identified eye protection/face shields were not consistently used in the decontamination area. Review of the audit tools dated 04/10/14, 07/10/14, 10/09/14 , and 01/08/15, showed staff failed to identify any issues with eye protection/face shields. 24. Review of the facility's, "Infection Prevention Surgical Ad Hoc Committee Meeting," minutes, dated 06/18/14, showed recommendations for the decontamination area included to continue with wearing PPE including face shield. 25. Observation on 03/31/15 at 10:15 AM showed Staff H cleaned surgical instruments. She did not wear protective goggles or a face mask. During an interview upon the observation, Staff H stated that she could not see without wearing her glasses and could not wear her glasses with the goggles. Staff F, Licensed Practical Nurse, directed her to put on a face shield. 26. Review of the facility's policy titled, "Surgical Abortion Services," dated 10/10/14, showed: - Supplies must be checked monthly to ensure	L1128		

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	MOA-0014	A. BUILDING: _____ B. WING _____	03/31/2015

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L1128	Continued From page 8 adequate amount for anticipated care and to remove any expired supplies from active inventory. - This is done on the last day of the month or the first day of each successive month prior to the start of the clinic session. 27. Observation on 03/30/15 at 1:50 PM of the ultrasound room showed a can of hand sanitizer, expiration 12/14. 28. Observation on 03/30/15 at 2:15 PM of the medication refrigerator showed a box of Tempa-Dot (brand) thermometers, expiration 02/15. 29. During an interview on 03/30/15 at 2:28 PM, Staff C stated that the thermometers had expired. 30. Observation on 03/30/15 at 3:12 PM of the second ultrasound room showed a can of hand sanitizer, expiration 02/15. During an interview upon the observation, Staff C stated that the hand sanitizer was expired. 31. Observation on 03/30/15 at 3:15 PM of ultrasound room C showed the examination table had a T-shaped tear in the middle of the pad, on the left side of the bed, approximately 6-inches high by 5-inches wide and an approximately 7-inch long linear tear on the right side. The tears exposed the foam core of the pad in several places leaving an uncleanable surface. During an interview upon the observation, Staff C stated that she had ordered a new table top pad approximately two weeks prior. 32. During an interview on 03/31/15 at 2:15 PM,	L1128		

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L1128	Continued From page 9 Staff C stated that: - Approximately two weeks prior another staff member asked for things needed and she had requested a new table top pad. - A large patient sat on the table and the table top pad split but she did not recall when this occurred. - They had not ordered a replacement table top pad. - She could not find any documentation to show they had identified they needed to replace the table top pad. 33. Observation on 03/30/15 at 1:50 PM of the ultrasound room C showed the cloth pillow on the table was covered with a torn, unzipped plastic pillow cover and a cloth pillow case. Approximately 3 inches of the cloth pillow was exposed. The exposed edge of the pillow showed a noticable gray discoloration while the remainder of the pillow that was protected by the plastic cover was white. 34. Observation on 03/30/15 at approximately 3:20 PM of procedure room #1 showed the cloth pillow on the table was covered with an unzipped plastic pillow cover and a cloth pillow case. The exposed end of the pillow was not covered by the plastic pillow case. 35. Observation on 03/30/15 at approximately 3:25 PM of procedure room #2 showed the cloth pillow on the table was covered with a cloth pillow case, leaving an uncleanable surface. 36. During an interview on 03/30/15 at approximately 3:20 PM, Staff E, Sonographer (Ultrasound Technician), stated that she changed the pillow case covers after each patient.	L1128		

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L1128	Continued From page 10 37. Review of the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2003, showed: - Microorganisms proliferate in environments wherever air, dust and water are present; and - Dry conditions favor gram-positive bacteria in dust and on surfaces. 38. Review of the facility's undated policy titled, "Environmental Cleaning of Clinical Areas: Policy and Procedure," showed: - At the beginning of each day or prior to the first patient interaction, all environmental clinical care areas will be cleaned and disinfected, including: patient dressing area, recovery rooms and exam/procedure rooms. 39. Review of the facility's,"Infection Prevention Ad Hoc Committee Meeting," minutes, dated 03/13/15 showed: -Identified areas of surgical services for daily, weekly, monthly, and periodic cleaning to included ultrasound rooms, procedure rooms; and recovery area. - Need to detail items for cleaning in the ultra sound rooms (i.e., identify equipment and furniture items to clean--exam table, lamps, other furniture, and wall items). 40. Review of the facility's, "Infection Prevention Committee Meeting," minutes, dated 11/12/14, showed staff identified that they needed to include environmental cleaning expectation in the general standard requirement section of their OSHA manual. 41. Observation on 03/30/15 at approximately 2:15 PM of the pre/postoperative medication	L1128		

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L1128	Continued From page 11 refrigerator showed the front of the refrigerator was dirty and there was tape and adhesive on the refrigerator, leaving an uncleanable surface. 42. Observation on 03/30/15 at 2:21 PM of the pre/post-operative area nurses' station showed a cabinet with packages of intravenous (IV-small catheter inserted into a vein for administering medication and fluid) administration tubing. There was a layer of dust on the shelves that left a easily visible mark when a finger was pulled through. 43. During an interview on 03/30/15 at 2:27 PM, Staff C stated that the cabinet shelves were dusty. 44. Observation on 03/30/15 at 2:30 PM of the pre/postoperative area showed there was tape, adhesive, and/or peeling labels on the cabinets and clip boards on the wall, leaving an uncleanable surface. 45. Observation on 03/30/15 at 2:40 PM of procedure room #3 showed a drawer with dust and debris inside and adhesive residue and/or torn labels on the outside of the cabinets and/or drawers. 46. Observation on 03/30/15 at 2:43 PM of procedure room #1 showed adhesive residue and tape on the cabinet doors and drawers. 47. During an interview on 03/30/15 at 2:45 PM, Staff C stated that they would have to remove the tape and adhesive residue. 48. Observation on 03/30/15 at 2:50 PM of the clean side of the sterilization area showed: - Brownish residue in one cabinet and on the floor	L1128		

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L1128	Continued From page 12 in front of the cabinet; - Tape and/or adhesive residue on the cabinet doors ; and - A drawer in the corner of the room which contained nonsterile surgical instruments with dust and debris in the drawer. During an interview upon the observation, Staff C stated that it was obvious no one had been in the drawer in a long time. 49. During an interview on 03/31/15 at 10:35 AM, Staff H stated that she did not clean the drawers and the instruments in the drawer were extra instruments. 50. Observation on 03/30/15 at 3:12 PM of the ultrasound room showed: - A plastic tray holding protective bed pads. The tray had a layer of dust that left a mark when a finger was pulled through. - An ultrasound machine (used to obtain images of the fetuses) with a layer of dust on the control panel that left an easily visible mark when a finger was pulled through. - Tape on the side and base of the ultrasound machine. 51. During interviews upon the observation, Staff E stated that she had just dusted the room that morning and dusted constantly but the room got dusty again quickly. Staff A, Chief Operating Officer, stated that the tape could be removed. 52. Observation on 03/30/15 at 3:55 PM of the hallway outside the sterilization area showed there was a wheelchair with a layer of dust on the frame that left an easily visible mark when a finger was pulled through.	L1128		

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L1128	Continued From page 13 During an interview upon the observation, Staff C stated that they often used the wheelchair. 53. Review of the facility's, "OSHA and Laboratory Procedure Manual," dated 12/14/14 showed: - Each employee is responsible to disinfect and decontaminate work surfaces at the end of each shift; and - Work surfaces included countertops, exam tables, mobile medication carts, etc. (Note: There were no directions on when and/or how often to clean the laboratory refrigerator.) 54. Review of the facility's, "Quality Management Checklist," policy dated 12/14/14, showed: - Check refrigerator temperatures daily; and - Clean/disinfect laboratory equipment/furniture. (Note: There were no directions on when and/or how often to clean the laboratory refrigerator.) 55. Observation on 03/30/15 at 3:00 PM of the laboratory refrigerator, showed there were several dark strands of hair and dust on the bottom shelf of the refrigerator. During an interview upon the observation, Staff C confirmed there was hair in the refrigerator. 56. During an interview on 03/30/15 at 3:10 PM, Staff D, HCA, stated that: - He had been employed approximately 1 and 1/2 years. - He had never cleaned the refrigerator; - He did not recall if it was one of his duties; and - Maybe people that had worked there longer cleaned it.	L1128		
L1136	19 CSR 30-30.060(1)(B)(12) The administrator shall be responsible	L1136		

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L1136	Continued From page 14 The administrator shall be responsible for ensuring that the provisions of Chapter 188, Regulation of Abortions, RSMo 1986 are adhered to. This regulation is not met as evidenced by: Based on policy review and interview the facility failed to ensure that all provisions of Chapter 188 were adhered to regarding the reporting of pathologist's reports and the submission to the Missouri Department of Health. The abortion facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases. Findings included: 1. Review of the facility's policy titled, "Surgical Abortion Services," dated 10/10/14, showed per Missouri law, all fetal tissue is sent to a pathology laboratory for evaluation. 2. Review of Missouri State Statute 188.047 showed that a representative sample of tissue removed shall be submitted to a pathologist who shall file a copy of the tissue report with the state Department of Health and Senior Services. 3. During an interview on 03/31/15 at 11:00 AM Staff A, Chief Executive Officer, stated that the pathology service utilized by the facility did not submit pathology specimen reports to the Missouri Department of Health and Senior Services.	L1136		
L1184	19 CSR 30-30.060(4)(D) The following laboratory procedures shall	L1184		

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L1184	Continued From page 15 The following laboratory procedures shall be performed on every abortion patient: hematocrit; urinalysis, including pregnancy test; and Rh typing. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to date glucometer (device used for testing the blood sugar level) test strips (used to place a drop of blood to test the blood sugar). The Abortion Facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases. 1. Review of the facility's undated OneTouch UltraSmart (brand - glucometer) Owner's Booklet showed: - Write the discard date (3 months after first opening the vial) on the vial label when you first open it. Discard remaining OneTouch Ultra Test Strips after the discard date. - Do not use test strips beyond the expiration (printed on the package) or discard date, whichever comes first, because they may cause inaccurate results. 2. Review of the facility's laboratory log showed the last blood glucose test had been completed on 03/28/15. 3. Observation on 03/30/15 at 3:00 PM in the laboratory showed a OneTouch UltraSmart glucometer. Staff failed to date the bottle of test strips to show when they were to be discarded. Instructions on the bottle showed, "Discard six months after opening." There was a line on the bottle to write the discard date, which had been left blank. During an interview upon the observation, Staff D,	L1184		

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L1184	Continued From page 16 Health Center Assistant, who was working in the lab, stated that he had no idea when the test strips had been opened.	L1184		

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L 000	Initial Comments An on-site, unannounced, state licensure survey was conducted from 03/30/15 to 03/31/15. An onsite complaint investigation for complaint MO00100367 was also conducted and the complaint was found to be unsubstantiated. See below for findings:	L 000		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Restrict multi-dose vials to a centralized medication area separate from the patient treatment area; - Ensure expired medications were not available for patient use; - Have accessible and follow manufacturer's instructions for use; - Monitor the humidity in the clean and dirty instrument processing area; - Protect sterile items from dust and moisture by placing a solid barrier on the bottom shelves;	L1128		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE
Carol Washington 3.23.15 Vice President of Patient Services and Education

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128	<u>Restriction of multi-dose vials to centralized medication area</u> PPSLR Policy titled Pharmaceutical Services reviewed and revised to be consistent with Infection Prevention Manual to include in the policy that multi-dose medications should be restricted to a centralized medication area from patient treatment areas. Plan to: -Identify restricted centralized medication area -All staff memo of restricted centralized medication area location -Staff training for Pharmaceutical Services Policy to include: 1. Revised procedure for restricted medication area for multi-dose medications 2. Procedural review of usage, storage & discarding of multi-dose medications and controlled substance inventory management -Include in developed Weekly Site Review Form and revised QM Monthly Site System Review multi-dose mediations use, management and restriction to centralized area	by 5/31/2015	Dir of Quality & Training (for Pharmaceutical Policy) Dir of Surgical Services	Supervisory observation monitoring and completion of Site Weekly and Monthly Audit Forms Staff sign attendance training sheet for: Revised Pharmaceutical Review of Review of multi-dose medications only in restricted areas	L1128 F-1 Pharmaceutical Services Protocol
L1128	<u>Ensure expired medications not available for patient use</u> Plan to: -Conduct staff review training of 1. Expired inventory management, 2. Daily inventory management of controlled substances at the beginning and end of clinic day 3. Storage of pharmaceutical supplies in non-clinical treatment areas.	by 5/31/2015	Dir of Surgical Services	-Completion of weekly and monthly site audits of emergency supply logs that include expired medication management by Health Center Assistants/MAs. -Surgical Nurse Coordinator reviews and signs weekly & monthly site audits -Staff sign attendance training sheet conducted by Supervisor of Nursing/Clinical Manager for expired inventory and management of pharmaceutical supplies -Document observational site audits	L1128 F-4 QM Monthly Site System Review

Americans United for Life

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128	Continued from page 2 -Perform observational site audits that includes expired merchandise, pharmaceutical inventory management & ,inventory storage criteria for procedure rooms and merchandise in active inventory areas			-Report audit results to Dir of Surgical Services -Include in new staff onboarding orientation/training medication inventory management	
L1128	Have accessible and follow manufactures instruction for use Plan to : -Ensure equipment maintenance & operational manuals are accessible on site -Revise Clinical Area Testing Manual in Equipment and Calibration Section of Autoclave Operation to include 1. Daily door gasket cleaning 2. Weekly air jet cleaning & chamber cleaning 3. Monthly safety valve cleaned and checked 4. Annually replace door gasket and inspect locking device for wear -Ensure documentation by independent calibration & repair vendor technician during annual equipment calibration inspection specific service check items/systems performed including replacement of rubber door gasket -Revise autoclave maintenance documentation for daily, weekly, monthly and annual completed on the Autoclave Cleaning & Testing Log -Conduct staff review training of autoclave operational checks of daily door gasket cleaning, weekly air jet cleaning and monthly safety valve check	by 5/31/2015 by 5/31/2015	Dir of Quality & Training Dir of Quality & Training	-Revise QM Monthly Site System Review form to include equipment maintenance & operational manuals available to staff -Annual 2015 calibration inspection report by external company lists specific items/systems checked for safety and proper operations (next annual calibration due 8/2015) -Continue with annual equipment calibration listed as a CQRM (Compliance Quality Risk Management) work plan activity -Surgical Nurse Coordinator/Infection Prevention Committee Member monthly monitoring & signature acknowledgement on Autoclave Cleaning & Testing log completion -Staff sign attendance training sheet for autoclave operational checks for daily door gasket cleaning, weekly air jet cleaning and monthly safety valve check	N/A

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128	Monitor the humidity in the sterilization and decontamination instrument processing area Plan to: -Purchase humidistat to monitor humidity level of decontamination and sterilization areas -Revise room temperature log to include daily documentation of relative humidity -Train appropriate staff on monitoring and documenting daily humidity	by 5/31/2015	Dir of Surgical Services	-Supervisory monitoring and signature on form indicating completion by appropriate staff - Include in new staff onboarding orientation/training management of room temperature to include monitoring of humidity level	N/A
L1128	Protect sterile items from dust and moisture by placing a solid barrier on the bottom shelves Plan to: -Purchase and install protective barrier on bottom shelf of sterile instrument storage rack	by 5/31/2015	Dir of Surgical Services	Include on QM Monthly Site System Review form audit item to check for protective shelf barrier on bottom shelf of sterile instrument storage rack	L1128 F-4 QM Monthly Site System Review
L1128	Ensure staff wear personal protective equipment appropriate to the task performed Plan to: -Review and re-train staff that work in decontamination area of PPE selection and use during tasks where possible exposure to potentially infectious materials anticipated	by 5/31/2015	Dir of Surgical Services	-Decontamination staff sign training attendance sheet for review of selection & use of PPE -Complete QM Monthly site review audit that includes this criteria	N/A
L1128	Replace worn patient-care items with functional easily cleanable surfaces Plan to: -Replace ultrasound room C examination table upholstery covering -Ensure cleanable surfaces, free from tape& adhesive for cabinets, refrigerators, clip boards -Include in QM Monthly Site System Review Audit item of cleanable surfaces for equipment and patient care items	by 5/31/2015	Dir of Surgical Services	-Include on QM Monthly Site System Review form audit item for cleanable surfaces of patient care areas/items	L1128 F3 repair invoice attached

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128	Ensure clean, free from dust surfaces of equipment, drawers, shelves and other horizontal surfaces Plan to: -Review and re-train staff of environmental area furniture and equipment potential for dust and cleaning expectation -Establish standard for pillows completely covered with plastic covers -Replaced pillows with plastic , non-permeable covers and re-train staff for cleaning standard -Revise Quality Management Checklist, include in Clinical Area Testing Manual I Equipment Operation and Management section Refrigerator cleaning daily and completion of Laboratory Daily Cleaning Checklist -Train staff on Laboratory Daily Cleaning Checklist	by 5/31/2015	Dir of Surgical Services	-Include on QM Monthly Site System Review form audit item to check for dust -Monitoring for completion Laboratory Daily Cleaning Checklist by staff of daily initials and weekly supervisory signature - Staff sign attendance training sheet for Laboratory Daily Cleaning Checklist conducted by Clinical Manager -Laboratory staff orientation onboarding documentation includes criteria for laboratory daily cleaning	L1128 F-4 QM Monthly Site System Review
L1136	Ensure the external pathology service submit tissue reports to the Missouri Department of Health and Senior Services Plan to: -Formalize agreement with letter of understanding from pathologist to file a copy of tissue reports with the State Department of Health and Human Services	by 5/31/2015	CEO	-Include requirement of external pathology service submitting tissue report to Missouri Department of Health and Human Services in RHS of PPSLR service standards. - Director of Quality and Training will ensure pathologist agreement letter acknowledgement on file as part of annual review of contractual agreements	N/A
L1184	Ensure dating of glucometer test strips for discard date Plan to: -Staff review of procedure for dating on the bottle of test strips the expiration date when they should be discarded	by 5/31/2015	Clinical Manager	-Observation audit of dating documentation of written discard date during QM Monthly Site System Review	L1128 F-4 QM Monthly Site System Review

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PHARMACEUTICAL SERVICES

7.1.1 Policies and Procedures – **must** include

Formulary of all drugs stocked in the affiliate that is reviewed annually

A. Consider the potential for medication errors when developing formulary. Look-alike, sound-alike drugs should be identified as being at "high risk" for potential error. Extra steps should be taken to ensure safety.

FYI - Look-alike, Sound-alike (LASA) Medications

List of additional therapeutic/pharmacologic classifications of drugs that may be ordered for clients to obtain at outside pharmacies

Provision of pharmaceuticals in accordance with all state/local laws and regulations

A drug control system that covers the interval from the time pharmaceuticals are ordered until they are provided to the client

Inspection of all drug storage areas to remove expired drugs

Designation of which staff may have access to bulk storage areas

Management of pharmaceutical product irregularities and drug and device recalls

7.1.2 Procurement

I. There **must** be a written order for all drugs/pharmaceuticals/chemicals brought into the affiliate:
   A. A copy of the purchase order or the prescription **must** be kept in the affiliate's files. A signed receipt **must** be obtained for pharmaceuticals shipped from a central location to outlying centers or clinics. If delivery is made by affiliate staff, a signed receipt is not necessary.
   B. Controlled substance order and receipt records **must** be filed separately from the other pharmaceutical purchase records.

II. If pharmaceuticals are routinely purchased from a community or hospital pharmacy and if the items are not supplied in manufacturer original containers, there should be a written contract specifying, at a minimum, requirements for labeling.

III. If available, pharmaceuticals should be purchased in manufacturer prepared unit-of-use packages.

IV. Only drugs and devices approved by the Federal Food and Drug Administration (FDA), and manufactured for sale in the United States may be used. Affiliates may not import drugs and/or medical devices from other countries for use in their health centers.

7.1.3 Storage

I. Access
   A. The bulk storage area **must** be secure.
   B. Controlled substances **must** be locked and in a secure area at all times.
   C. Access to pharmaceuticals dispensed from within client care areas should be limited to health care providers responsible for dispensing these items.

How to store

   D. Arrange medications so that the oldest stock is used first.
   E. Do not store look-alike, sound-alike medications alphabetically. Store them out of order or in a separate location.[R1]
   F. Pharmaceuticals meant for internal use **must** be stored separately (i.e., on a separate shelf) from those for external (i.e., topical) use only.
   G. All prescription medications should be stored in containers that protect them from light.
   H. All manufacturer recommendations for storage **must** be followed.

Storage for contraceptive vaginal ring (CVR)

I. An expiration date **must** be on the label of each ring package. If needed, use the adhesive labels provided in the carton.
J. For rings that will not be refrigerated, the adhesive label **must** be applied directly over the pre-existing expiration date on each cachet pouch (and on the outer carton). This date should not exceed either 4 months from the date of dispensing, or the product expiration date, whichever comes first.
K. For refrigerated NuvaRing, the product expiration date may be used.
L. NuvaRing packages that need to be refrigerated **must** be clearly marked.
M. NuvaRing should never be stored in direct sunlight or at temperatures above 30°C (86°F).

Store Mifepristone and misoprostol at room temperature.

Storage of multi-dose vials

N. Unopened multi-dose vials – **must** follow manufacturers' recommendation for storage
O. Opened multi-dose vials
    1. When a multi-dose vial is used, appropriate infection prevention procedures to prevent contamination should be employed.[R2]
    2. Vials **must** be discarded if there is evidence of contamination.
    3. If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial **must** be dated and discarded in accordance with manufacturer's instructions and state/local regulations.
    4. If no specific guidelines are provided, CDC recommends discarding the vial within 28 days.[R2]
    5. Syringes taken from multi-dose vials must be labeled with medication name, date, time and staff initials. If not used within 24 hours, it must be discarded.
    6. Open vials of misoprostol should be discarded after 30 days.
    7. Multi-dose vials (once opened) shall be kept in centralized location, (RHS-the nursing station in Recovery, HC- laboratory area).
P. Single use medications are used for one client only and are discarded after use on each patient.

Prescription pads

Q. Must be secured in medication cabinet when not in use.

Americans United for Life

Reproductive Health Services of Planned Parenthood of the St. Louis Region
4251 Forest Park Avenue, 63108 314-531-7526

QM Monthly Site System Review **Month_____/_____**
To be completed monthly by Director of Surgical Services/Delegate

Site_____ **Auditor**_____

Date	System Reviewed	Guidelines Met	Guidelines Not Met
	Exit and pathways in the surgical center are clear		
	Computer passwords are secured and not visible		
	Areas free from dust &debris, tape: Surfaces of medical equipment, cabinets & drawers, medication refrigerator, ceiling vents		
	Universal Precautions used by all staff (Including before & after pt contact)		
	Personal Protective Equipment available & appropriately used (masks, face shield lab coats, gloves in various sizes, face shield, vinyl gloves, utility gloves)		
	Steps to follow when an accident occurs involving workers compensation is posted and forms readily available for staff		
	Emergency equipment in the surgical center: ***(audited by a supervisor_____)*** *(initials)* Resuscitative equipment First Aid Kit Spill Kit/Supplies Flashlights and back up lighting operable Ammonia Capsules Defibrillator Exit lighting operable Cart with emergency supplies & weekly checklist current		
	Fire Extinguishers easily accessible, charged, inspection current		
	MSDS Log current with supplies that are used in the surgical center		
	Housekeeping: Procedure rooms & equipment clean Overall cleanliness of site (floors, counters, equipment, regular and biohazard trash not over flowing containers) Bleach/Water solution in 1:10 ratio or disinfectant solution with documented change Surface decontamination performed per infection control protocol		
	Staff use protective equipment for patient interactions, cleaning of rooms and equipment management as necessary		
	All specimens labeled, handled appropriately and staff follow general packaging requirements.		
	Disposed specimen containers with PHI de-identified before disposal		
	Single use suction tubing discarded after each procedure		
	Decontamination receiving and clean/sterilized items separated		
	Sterile Instrument Storage-protective shelve barrier present on bottom shelf		
	Checklist completed by assigned staff -Daily lab refrig temp - Decontamination & Sterilization Procedures documented -Sterilizer indicator with each autoclave batch -Weekly & Monthly autoclave cleaning & testing Weekly Spore Testing documented for each autoclave machine		
	NO expired merchandise in active inventory areas (such as storage rooms or drawers; procedure & patient care rooms &shelving; laboratory room, laboratory/patient supply refrigerator; decontamination, sterilization and front desk/reception areas)		
	Multi-use medication/vials are dated upon opening with discard date		
	Controlled substance log/appropriate documentation completed when applicable		
	Sharp Collectors placed on shelves or in wall brackets		
	Potentially infectious waste(i.e. blood soaked products, IV tubing with blood, tissue, POC) **in appropriate containers**		
	Disposal of sharps (i.e. needles, lancets, capillary tubes syringes with needles, used microscopic slides & cover slips, etc.) **in appropriate sharp containers**		
	Unexpired cleaning supplies & equipment accessible to staff		
	Clinic Procedure and Laboratory Practices Manual in surgical center		
	Proficiency Log in place and current for newly hired staff		
	Workstations free of hazards		

Comments:

Corrective Actions:

Invoice

Superior Upholstery
38 Circle Way Drive
ST PETERS, MO 63376
United States
Tel: 314-607-8049

Bill to:
Planned Parenthood
4251 Forest Park Ave
St Louis, MO

Invoice number: 89389
Invoice date: April 15, 2015
Due date: May 15, 2015

Amount due : **$350.00**

NOTES
If you have any questions about this invoice, please call Dan Lonero at 314-607-8049.Email to Superioruph@gmail.com

Product/Service	Qty	Price	Amount
Exam Table Recovered	1	$350.00	$350.00

Total **$350.00**
Amount due **$350.00**

Thank you for your business.

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/31/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNE	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced, state licensure survey was conducted from 03/30/15 to 03/31/15. An onsite complaint investigation for complaint MO00100367 was also conducted and the complaint was found to be unsubstantiated. See below for findings:	L 000		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Restrict multi-dose vials to a centralized medication area separate from the patient treatment area; - Ensure expired medications were not available for patient use; - Have accessible and follow manufacturer's instructions for use; - Monitor the humidity in the clean and dirty instrument processing area; - Protect sterile items from dust and moisture by placing a solid barrier on the bottom shelves;	L1128		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE
Carol Washington 3.23.15 Vice President of Patient Services and Education

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128	<u>Restriction of multi-dose vials to centralized medication area</u> PPSLR Policy titled Pharmaceutical Services reviewed and revised to be consistent with Infection Prevention Manual to include in the policy that multi-dose medications should be restricted to a centralized medication area from patient treatment areas. Plan to: -Identify restricted centralized medication area -All staff memo of restricted centralized medication area location -Staff training for Pharmaceutical Services Policy to include: 1. Revised procedure for restricted medication area for multi-dose medications 2. Procedural review of usage, storage & discarding of multi-dose medications and controlled substance inventory management -Include in developed Weekly Site Review Form and revised QM Monthly Site System Review multi-dose mediations use, management and restriction to centralized area	by 5/31/2015	Dir of Quality & Training (for Pharmaceutical Policy) Dir of Surgical Services	Supervisory observation monitoring and completion of Site Weekly and Monthly Audit Forms Staff sign attendance training sheet for: Revised Pharmaceutical Review of Review of multi-dose medications only in restricted areas	L1128 F-1 Pharmaceuti cal Services Protocol
L1128	<u>Ensure expired medications not available for patient use</u> Plan to: -Conduct staff review training of 1. Expired inventory management, 2. Daily inventory management of controlled substances at the beginning and end of clinic day 3. Storage of pharmaceutical supplies in non-clinical treatment areas.	by 5/31/2015	Dir of Surgical Services	-Completion of weekly and monthly site audits of emergency supply logs that include expired medication management by Health Center Assistants/MAs. -Surgical Nurse Coordinator reviews and signs weekly & monthly site audits -Staff sign attendance training sheet conducted by Supervisor of Nursing/Clinical Manager for expired inventory and management of pharmaceutical supplies -Document observational site audits	N/A

Americans United for Life

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128	Continued from page 2 -Perform observational site audits that includes pharmaceutical inventory management & inventory storage criteria for procedure rooms and patient treatment areas			-Report audit results to Dir of Surgical Services -Include in new staff onboarding orientation/training medication inventory management	
L1128	<u>Have accessible and follow manufactures instruction for use</u> Plan to : -Ensure equipment maintenance & operational manuals are accessible on site -Revise Clinical Area Testing Manual in Equipment and Calibration Section of Autoclave Operation to include 1. Daily door gasket cleaning 2. Weekly air jet cleaning & chamber cleaning 3. Monthly safety valve cleaned and checked 4. Annually replace door gasket and inspect locking device for wear -Ensure documentation by independent calibration & repair vendor technician during annual equipment calibration inspection specific service check items/systems performed including replacement of rubber door gasket -Revise autoclave maintenance documentation for daily, weekly, monthly and annual completed on the Autoclave Cleaning & Testing Log -Conduct staff review training of autoclave operational checks of daily door gasket cleaning, weekly air jet cleaning and monthly safety valve check	by 5/31/2015 by 5/31/2015	Dir of Quality & Training Dir of Quality & Training	-Revise QM Monthly Site System Review form to include equipment maintenance & operational manuals available to staff -Annual 2015 calibration inspection report by external company lists specific items/systems checked for safety and proper operations (next annual calibration due 8/2015) -Continue with annual equipment calibration listed as a CQRM (Compliance Quality Risk Management) work plan activity -Surgical Nurse Coordinator/Infection Prevention Committee Member monthly monitoring & signature acknowledgement on Autoclave Cleaning & Testing log completion -Staff sign attendance training sheet for autoclave operational checks for daily door gasket cleaning, weekly air jet cleaning and monthly safety valve check	N/A

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L1128	Monitor the humidity in the sterilization and decontamination instrument processing area Plan to: -Purchase humidistat to monitor humidity level of decontamination and sterilization areas -Revise room temperature log to include daily documentation of relative humidity -Train appropriate staff on monitoring and documenting daily humidity	by 5/31/2015	Dir of Surgical Services	-Supervisory monitoring and signature on form indicating completion by appropriate staff - Include in new staff onboarding orientation/training management of room temperature to include monitoring of humidity level	N/A
L1128	Protect sterile items from dust and moisture by placing a solid barrier on the bottom shelves Plan to: -Purchase and install protective barrier on bottom shelf of sterile instrument storage rack	by 5/31/2015	Dir of Surgical Services	Include on QM Monthly Site System Review form audit item to check for protective shelf barrier on bottom shelf of sterile instrument storage rack	N/A
L1128	Ensure staff wear personal protective equipment appropriate to the task performed Plan to: -Review and re-train staff that work in decontamination area of PPE selection and use during tasks where possible exposure to potentially infectious materials anticipated	by 5/31/2015	Dir of Surgical Services	-Decontamination staff sign training attendance sheet for review of selection & use of PPE -Complete QM Monthly site review audit that includes this criteria	N/A
L1128	Replace worn patient-care items with functional easily cleanable surfaces Plan to: -Replace ultrasound room C examination table upholstery covering -Ensure cleanable surfaces, free from tape& adhesive for cabinets, refrigerators, clip boards -Include in QM Monthly Site System Review Audit item of cleanable surfaces for equipment and patient care items	by 5/31/2015	Dir of Surgical Services	-Include on QM Monthly Site System Review form audit item for cleanable surfaces of patient care areas/items	L1128 F3 repair invoice attached

A	B	C	D	E	F
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L1128	Ensure clean, free from dust surfaces of equipment, drawers, shelves and other horizontal surfaces Plan to: -Review and re-train staff of environmental area furniture and equipment potential for dust and cleaning expectation -Establish standard for pillows completely covered with plastic covers -Replaced pillows with plastic , non-permeable covers and re-train staff for cleaning standard -Revise Quality Management Checklist, include in Clinical Area Testing Manual I Equipment Operation and Management section Refrigerator cleaning daily and completion of Laboratory Daily Cleaning Checklist -Train staff on Laboratory Daily Cleaning Checklist	by 5/31/2015	Dir of Surgical Services	-Include on QM Monthly Site System Review form audit item to check for dust -Monitoring for completion Laboratory Daily Cleaning Checklist by staff of daily initials and weekly supervisory signature - Staff sign attendance training sheet for Laboratory Daily Cleaning Checklist conducted by Clinical Manager -Laboratory staff orientation onboarding documentation includes criteria for laboratory daily cleaning	N/A
L1136	Ensure the external pathology service submit tissue reports to the Missouri Department of Health and Senior Services Plan to: -Formalize agreement with letter of understanding from pathologist to file a copy of tissue reports with the State Department of Health and Human Services	by 5/31/2015	CEO and	-Include requirement of external pathology service submitting tissue report to Missouri Department of Health and Human Services in RHS of PPSLR service standards. - Director of Quality and Training will ensure pathologist agreement letter acknowledgement on file as part of annual review of contractual agreements	N/A
L1184	Ensure dating of glucometer test strips for discard date Plan to: -Staff review of procedure for dating on the bottle of test strips the expiration date when they should be discarded	by 5/31/2015	Clinical Manager	-Observation audit of dating documentation of written discard date during QM Monthly Site System Review	N/A

PHARMACEUTICAL SERVICES

7.1.1 Policies and Procedures – **must** include

Formulary of all drugs stocked in the affiliate that is reviewed annually

A. Consider the potential for medication errors when developing formulary. Look-alike, sound-alike drugs should be identified as being at "high risk" for potential error. Extra steps should be taken to ensure safety.

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    4. If no specific guidelines are provided, CDC recommends discarding the vial within 28 days.[R2]
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Americans United for Life

Invoice

Superior Upholstery
38 Circle Way Drive
ST PETERS, MO 63376
United States
Tel: 314-607-8049

Bill to:
Planned Parenthood
4251 Forest Park Ave
St Louis, MO

Invoice number: 89389
Invoice date: April 15, 2015
Due date: May 15, 2015

Amount due : **$350.00**

NOTES
If you have any questions about this invoice, please call Dan Lonero at 314-607-8049.Email to Superioruph@gmail.com

Product/Service	Qty	Price	Amount
Exam Table Recovered	1	$350.00	$350.00

Total **$350.00**
Amount due **$350.00**

Thank you for your business.

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 30, 2015

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***POC Approval***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Licensure Survey conducted on ***March 31, 2015*** has been received in our office and forwarded to the surveyor(s). We want you to know the surveyor(s) has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

June 15, 2015

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Revisit Survey***

Dear Mary Kogut:

Please see attached results of the recent follow-up survey of ***June 9, 2015***. This relates to the Licensure survey conducted ***March 31, 2015***. Your facility is now in compliance with the Medicare and Licensure requirements for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 06/09/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced revisit survey was conducted on 06/09/15. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	{L 000}		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

January 22, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Offsite Self Report Review***

Dear Mary Kogut:

An offsite investigation was conducted from ***01/11/16*** to ***01/12/16***. Please see attached results. Your facility was found to be in compliance with the ***Licensure*** requirements for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 01/12/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted from 01/11/16 to 01/12/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00110832 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 02/10/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An investigation was conducted from 02/10/16 to 03/11/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00111719 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30-060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 29, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***March 16, 2016*** in connection with the ***State Licensure*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/16/2016

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L 000	Initial Comments An onsite, unannounced state licensure survey to determine compliance with 19 CSR 30-30.050 through 19 CSR 30-30.070 for Abortion Facilities was conducted from 03/14/16 to 03/16/16. See below for findings:	L 000		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to: - Follow the manufacturer's instructions for cleaning two of two autoclaves (sterilizers); - Follow the manufacturer's instructions for biological testing (used to monitor steam sterilizers); - Have a procedure in place to prevent cross contamination and separation of contaminated instruments by space; - Follow the manufacturer's instructions for packaging instruments for sterilization; - Restrict multi-dose vials to a centralized	L1128		

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L1128	Continued From page 1 medication area separate from the procedure room; - Restrict single-dose vials/ampoules to single patient use; - Ensure a sanitary environment was preserved in the sterilization rooms and sterile supply room; - Ensure expired supplies were not available for use; - Ensure the glucometer (instrument for testing the blood sugar level) was approved by the manufacturer for clinical use (use on multiple patients); - Ensure medication refrigerators temperatures were maintained to provide stable medication; and - Ensure equipment used for patient care was approved for use in healthcare facilities. The Abortion Facility does an average of 424 cases per month. On the first day of the survey, there were 32 cases. Findings included: 1. Review of the American National Standards Institute (ANSI)/Association of the Advancement of Medical Instrumentation (AAMI) document titled, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities, ST79," dated 2010, showed: - 9.4 Routine Care: Sterilizers should be inspected and cleaned daily according the manufacturer's written instructions. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written instructions. 2. Review of the Tuttnauer (manufacturer) undated document titled, "Operation & Maintenance Manual," showed:	L1128		

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L1128	Continued From page 2 - If the autoclave is not cleaned regularly, dirt and debris will build up and clog the tubing and valves. This dirt can also be transmitted to the instruments during sterilization. In addition, a layer of dirt on the stainless steel chamber traps moisture against the metal and will lead to the chamber becoming porous and failing. - It is recommended that your autoclave be cleaned with Chamber Brite (brand) once per week. - It is required that the air jet be cleaned once per week or more often if necessary, to remove any accumulated dirt and debris. 3. Review of the facility's Affiliate Risk Management Services (ARMS) Infection Prevention Manual, dated 08/15, showed infection prevention resources included AAMI and Association of PeriOperative Registered Nurses (AORN). 4. Review of the facility's document titled, "Sterilization Room Humidity, Temperature and Autoclave Maintenance Log," dated 02/16, showed staff failed to clean the chamber of Autoclave #1 the week of 02/23/16 through 02/27/16. 5. Review of the facility's document titled, "Sterilization Room Humidity, Temperature and Autoclave Maintenance Log," dated 03/16, showed: - Staff failed to clean the chamber of Autoclave #1 the week of 03/01/16 through 03/05/16. - Staff failed to clean the air jet of Autoclave #1 the week of 03/08/16 through 03/12/16. - Staff failed to clean the air jet of Autoclave #2 the week of 03/08/16 through 03/12/16.	L1128		

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L1128	Continued From page 3 6. Observation on 03/14/16 at 2:01 PM in the sterile processing room showed two Tuttnauer 3870M (model) autoclaves. The inside of the autoclaves was discolored with shades of brown spots. 7. During an interview on 03/14/16 at 2:04 PM, Staff B, Registered Nurse (RN), Vice President of Patient Services, confirmed the discoloration but stated that she thought the discoloration was due to the age of the sterilizers. 8. Review of the product insert for 3M (manufacturer) Attest (brand) Biological Indicator, dated 09/05, showed: - Attest biological indicators should be placed in an appropriate test tray or package, and be used to monitor every load. - Record the sterilized and control biological indicator results. 9. Review of the facility's ARMS Infection Prevention Manual, dated 08/15, showed: - Affiliates must check state/local requirements and manufacturer's recommendations. - For affiliates, a biological indicator process challenge device must be conducted every week in a health center providing family planning services and daily in a health center providing abortion/surgical services. - The results of the bacteriological test must be documented in a log book or file and maintained for three years (check state/local requirement). 10. Review of the facility's undated policy titled, "Spore Testing Biological Indicator," showed: - Attest biological indicators should be placed in an appropriate test tray or package, and be used to monitor weekly loads of autoclaves.	L1128		

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L1128	Continued From page 4 - Record the sterilized and control biological indicator results in quality management binder. 11. Review of the facility's biological indicator log dated 02/16 showed staff performed a biological indicator weekly and failed to perform a biological indicator with every load. 12. During an interview on 03/15/16 at 3:42 PM, Staff H stated that: - The biological indicator was normally run on Wednesday. - They never ran the biological indicator with every sterilization load. 13. Review of the ANSI and AAMI document titled, "ANSI/AAMI ST79:2010," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, dated 09/24/10, showed: - 3.2.3. The sterile processing department should be designed to separate areas in which contaminated items are received and processed from areas in which clean items are packaged, sterilized, and stored. Functional work areas should be physically separated by walls or partitions to control contaminants generated during the phases of reprocessing. 14. Observation on 03/15/16 at 3:00 PM in the decontamination room showed Staff H cleaned instruments. The pass-through window was opened to the instrument processing room during the cleaning process and a tray of previously cleaned instruments were setting on the ledge of the opened window. A blue wrap (used to wrap surgical instruments for sterilization) and gauze (included in sterilization packs) were setting on the counter on the other side of the window.	L1128		

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L1128	Continued From page 5 15. During an interview on 03/15/16 at 3:25 PM, Staff H stated that they left the window open all the time. 16. Review of the Chex-all II (brand) paper-plastic pouches (peel packs - used to contain instruments for sterilization) manufacturer's instructions printed on the box showed: - After placing the item into the pouch, release the liner strip covering the adhesive is peeled off, and the pouch paper is folded at the crease so that the adhesive is in contact with the plastic of the pouch. - Pressure is then applied to the folded part of the pouch to complete the sealing process. 17. Review of the manufacturer's instructions printed on the peel packs showed to insert item, peel off liner, re-fold along the crease (press down from center outward). 18. Observation on 03/14/16 at 1:43 PM in procedure room #1 showed four peel packs holding instruments to be used during the abortion procedure. The closure ends of the peel pouches were folded over past the crease and folded over multiple times. (The peel packs are made with a paper side and a plastic side so steam can penetrate and is not trapped in the pouch. When the peel packs are folded over, it makes a plastic to plastic cover that prevents the proper penetration and exhaust of the steam.) (Note: Manufacturer's instructions on these peel packs were as above.) 19. Observation on 03/14/46 at 2:00 PM in procedure room #3 of the supply cabinets	L1128		

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L1128	Continued From page 6 showed numerous peel packages containing instruments to be used during the abortion procedure. The closure ends of the peel pouches were folded over approximately two inches below the package crease and taped across the package. (Note: Manufacturer's instructions on these peel packs were as above.) 20. Observation on 03/14/15 at 2:06 PM in the sterile processing room showed shelves of instruments in peel pouches. Staff failed to fold many of these peel pouches on the crease and were folded over multiple times. (Note: Manufacturer's instructions on these peel packs were as above.) 21. During an interview on 03/15/16 at 3:12 PM, Staff H stated that she did not know why some people folded over the peel packs multiple times. 22. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care," dated 2014, showed: - To dedicate multi-dose vials to a single patient whenever possible; and - If multi-dose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). 23. Review of the CDC document titled, "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care," dated 2014, showed: - Do not administer medications from single-dose or single-use vials, ampoules, or bags or bottles	L1128		

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L1128	Continued From page 7 of intravenous solution to more than one patient. 24. Review of the facility's policy titled, "Infection Prevention Program," dated 12/14/14, showed: - Do not administer medications from single-dose or single-use vials, ampules, or bags or bottles of intravenous (small catheter inserted into a vein for administering medication and fluid) solution to more than one patient. - If multi-dose vials will be used for more than one patient, the vials should be restricted to a centralized medication area. 25. Review of the facility's policy titled, "Pharmaceutical Services," dated 06/14, showed: - Multi-dose vials (once opened) shall be kept in a centralized location. - Single-dose medications are used for one client only and are discarded after use on each patient. 26. Observation on 03/14/16 at 1:30 PM in Procedure Room #1 showed an opened, multi-dose vial of Lidocaine (anesthetic - numbs an area). During an interview upon the observation, Staff D, Director of Surgical Services, stated that opened, multi-dose vials were not usually kept in the procedure rooms. 27. Observation on 03/14/16 at 1:35 PM of Procedure Room #1's emergency medication box showed an opened, single-dose vial of Dextrose (a form of sugar for injection). During an interview on 03/14/16 at 1:37 PM, Staff D stated that single-dose vials were usually thrown away.	L1128		

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L1128	Continued From page 8 28. Observation on 03/14/16 at 1:50 PM of Procedure Room #3 showed an opened multi-dose vial of Lidocaine on the counter. During an interview upon the observation Staff B stated that the opened multi-dose vial should not have been in the procedure room. 29. Observation on 03/14/16 at 4:45 PM in the laboratory showed an opened, multi-dose vial of normal saline (sterile mixture of salt and water for injection) with an expiration date of 03/01/16. During an interview upon the observation, Staff B stated that she was not sure what the normal saline was used for. 30. Review of the CDC and the Healthcare Infection Control Practices Advisory Committee, "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2003, showed: - Microorganisms proliferate in environments wherever air, dust and water are present; and - Dry conditions favor gram-positive bacteria in dust and on surfaces. 31. Review of the AORN, "Guideline for Environmental Cleaning," dated 2015, showed: - Recommendation II. * The patient should be provided a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The	L1128		

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L1128	Continued From page 9 responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. - Recommendation II.b. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. - Recommendation IV. * Perioperative areas should be terminally cleaned. * Terminal cleaning and disinfection of the perioperative environment decreases the number of pathogens and the amount of dust and debris. - Recommendation IV.a. * Terminal cleaning and disinfection of perioperative areas, including sterile processing areas, should be performed daily when the areas are being used. - Recommendation IV.e. * Sterile processing areas should be terminally cleaned. * Sterile processing personnel conduct critical processes, such as decontaminating, assembling, and sterilizing surgical instrumentation, in support of operating and invasive procedure rooms. As such, the recommendations for terminal cleaning apply in sterile processing areas as in areas where surgical and other invasive procedures are performed. Furthermore, sterile processing areas where decontamination occurs have some of the highest risks for environmental contamination of all perioperative areas. Environmental cleaning in sterile processing areas is critical for reducing the risk of disease transmission from reservoirs of bloodborne pathogens and microorganisms in the decontamination environment.	L1128		

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L1128	Continued From page 10 - Recommendation IV.e.2. * All horizontal surfaces (e.g., sterilizers, countertops, furniture, shelving) should be damp dusted daily with an Environmental Protection Agency (EPA) registered disinfectant and a clean, low-linting cloth. - Recommendation V. * All areas and equipment that are not terminally cleaned should be cleaned according to an established schedule. * A clean environment will reduce the number of micro-organisms present. - Recommendation V.a.1. * Areas and items that should be cleaned on a schedule include clean and soiled storage areas, sterile storage areas, shelving and storage bins; corridors, including stairwells and elevators, walls and ceilings, privacy curtains, pneumatic tubes and carriers, sterilizers and loading carts, sterilizer service access rooms, unrestricted areas (e.g., lounges, waiting rooms, offices), and environmental services closets. 32. Review of the facility's policy titled, "Infection Prevention Manual," dated 12/14/14, showed as part of the infection prevention plan, (facility) has policies and procedures for routine cleaning and disinfection of environmental surfaces. 33. Review of the facility's undated policy titled, "Environmental Cleaning of Clinical Care Areas: Policy and Procedure," showed: - At the beginning of each day or prior to the first patient interaction, all environmental clinical care areas will be cleaned and disinfected. - Reprocessing and other sterile storage areas are to be cleaned according to the following schedule: * Clean all counters and floors daily.	L1128		

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L1128	Continued From page 11 (Note: The facility's policy referenced CDC.) 34. Observation on 03/14/16 at 11:28 AM of the shelving units in the sterile supply room showed: - Two blue plastic storage bins that contained oxygen masks. Dust and loose particles were observed in the bottom of the bins. - One blue plastic storage bin that contained nasal cannulas. Dust and loose particles were observed in the bottom of the bin. - One blue plastic storage bin that contained sterile IV tubing. Dust and loose particles were observed in the bottom of the bin. - One empty blue plastic storage bin. Dust and loose particles were observed in the bottom of the bin. 35. Observation on 03/14/16 at 2:25 PM in the sterile processing room showed stacks of peel pouches on the counter with off-white flecks over the pouches. Some of the flecks fell off when the peel pouches were moved. During an interview upon the observation, Staff D stated that once they go through the sterilization process, it would kill everything. 36. Observation on 03/14/16 at 2:32 PM in the sterile processing room showed dust/white flecks around autoclave #1 that left a mark when a finger was pulled through. 37. Observation on 03/15/16 at 3:24 PM in the sterile processing room showed: - The stack of peel pouches on the counter with off-white flecks on the pouches. - Dust/white flecks around autoclave #1. During an interview upon the observation, Staff H	L1128		

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L1128	Continued From page 12 stated that: - She was not sure what the off-white flecks were from. - She agreed there were white flecks and dust around autoclave #1. 38. During an interview on 03/14/16 at 2:35 PM, Staff B stated that they had a housekeeper on staff that was responsible for cleaning the blue storage bins. She agreed the bins had debris in the bottom of them. 39. Review of the AORN, "Guideline for Cleaning and Care of Surgical Instruments," dated 2015, showed: - Recommendation II.e.5. * External shipping containers and web-edged cardboard boxes may collect dust, debris, and insects during transport and may carry contaminants into the facility. 40. Review of the facility's undated policy titled, "Environmental Cleaning of Clinical Care Areas," showed: - Clean all counters and floors daily in the sterile storage areas; and - The patient care environment throughout the facility will be maintained in a state of cleanliness that meets professional standards in order to protect patients and healthcare personnel from potentially infectious microorganisms. 41. Review of the facility's ARMS Infection Prevention Manual, dated 08/15, showed: - Guidelines for the storage of sterile supplies; * Store clean supplies separately from sterile supplies; and * Store supplies 8 to 10 inches from the floor.	L1128		

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L1128	Continued From page 13 42. Observation on 03/14/16 at 1:55 PM in the decontamination room showed a stack of flattened corrugated boxes. During an interview upon the observation, Staff B stated that the boxes were used for products (of the abortions) to be sent out (to pathology). 43. Observation on 03/14/16 at 2:00 PM in the sterile supply room showed: - Shelving units mounted on all walls with the following items stored next to sterile supplies: * Three corrugated boxes labeled "BD Syringes" that contained individually packaged sterile syringes; * One corrugated box that contained sterile packages of IV catheters; * Five opened corrugated boxes labeled "IPAS Cannulae" that contained individually packaged uterine cannulas (a hollow tube that can be inserted into the body, often for delivery or removal of fluid); * One corrugated box that contained formalin (a colorless solution of formaldehyde in water, used chiefly as a preservative for biological specimens) filled specimen cups; and * One corrugated box that contained business office forms; - Two corrugated boxes on the floor that contained disposable patient bed sheets; and - One corrugated box on the floor that contained condoms. 44. Observation on 03/15/16 at 3:27 PM in the sterile processing room showed corrugated boxes on the floor and propped against the wall. During an interview upon the observation, Staff H stated that the boxes contained the blue wrap	L1128		

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L1128	Continued From page 14 used for instrument wrapping (for sterilization) but were too long to be stored inside the cabinets. 45. During an interview on 03/14/16 at 2:35 PM, Staff B stated that: - They had a housekeeper on staff that was responsible for cleaning the sterile supply room, including the floors; and - The corrugated boxes should not have been in the sterile supply room. 46. Review of the bottle of Metracide (manufacturer) Cidex OPA Plus (brand - used to high-level disinfect semi-critical items that come in contact with non-intact skin or mucous membranes) test strips showed, "Use within 90 days of opening." 47. Observation on 03/14/16 at 2:15 PM showed a bottle of Metracide Cidex OPA Plus test strips with 05/16 and "11/20/15 open" written on the bottle. (Note: The test strips expired 02/20/16.) During an interview upon the observation, Staff B stated that it looked like they were expired. 48. Observation on 03/14/16 at 4:40 PM in an ultrasound room showed a container of ultrasound gel with an expiration date of 12/15. During an interview upon the observation, Staff B confirmed that the ultrasound gel had expired. 49. Observation on 03/14/16 at 4:45 PM in the laboratory showed an opened Hemocue (device used to test blood) swab (used for disinfecting the Hemocue) with an expiration date of 08/09/14.	L1128		

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L1128	Continued From page 15 During an interview upon the observation, Staff B confirmed that the Hemocue swab had expired. 50. Review of the CDC, "Infection Prevention during Blood Glucose Monitoring and Insulin Administration," dated 05/02/12, showed whenever possible, blood glucose meters should not be shared. If they must be shared, the device should be cleaned and disinfected after every use, per manufacturer's instructions. If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared. 51. Review of the CDC, "Guideline for Disinfection and Sterilization in Healthcare Facilities," dated 2008, showed the Food and Drug Administration (FDA) had not cleared any high-level disinfectant with alcohol as the main ingredient. 52. Review of the TRUEbalance (brand) glucometer's Owner's Booklet showed: - The TRUEbalance Blood Glucose Monitoring System is for one person use ONLY; - DO NOT share your meter with anyone, including family members; and - ALL parts of the meter could carry blood-borne disease after use, even after cleaning and disinfection. 53. Review of the facility's policy titled, "Blood Glucose Testing with Glucometer," dated 06/25/15, showed: - Clean meter when visibly dirty; - Wipe meter with a clean, lint-free cloth dampened with 70% Isopropyl alcohol; and - Let meter air dry thoroughly before using to test.	L1128		

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L1128	Continued From page 16 The policy failed to list a procedure for disinfecting the glucometer. 54. During an interview on 03/15/16 at 1:30 PM, Staff B stated that: - She read the manufacturer's instructions for use manual for the glucometer; - The glucometer had not been approved for clinic use on multiple patients; and - They would purchase new multi-use glucometers. 55. Review of the facility's policy titled, "Laboratory Refrigerator," dated 05/03/15, showed: - Each site has two refrigerators for clinical operations, one for medical supplies. - The temperature should be checked and recorded twice daily. - The acceptable range is between 2 and 8 Celsius (36-46 degree Fahrenheit[F]). - If not in range, report to supervisor and document corrective action. 56. Observation on 03/14/16 at 2:00 PM in the pre-post area showed: - A refrigerator labeled patient medication refrigerator; - The refrigerator contained multiple boxes of Rhogam (a sterilized solution made from human blood used to prevent an immune response to Rh positive blood in people with an Rh negative blood type.) - The manufacturer's recommendation for storage of Rhogam showed: * Store at 2-8 degree Celsius (36-46 degree F). Do not freeze. 57. Review of the Medication Refrigerator	L1128		

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L1128	Continued From page 17 Temperature Logs for 02/16 showed direction for staff to monitor the temperatures daily. - The ideal temperature was 34-40 degrees F: - No temperature was recorded for 02/08/16, 02/11/16, 02/15/16, 02/18/16, 02/22/16, and 02/25/16; - Temperature was recorded out of range on nine of 18 recorded days based on the temperature log range of 34-40 degree F with no intervention recorded; - Temperature was outside the Rhogam manufacturer's recommended temperature range of 36-46 degree F for three of 18 recorded days; and - Temperatures were recorded below freezing (32 degree F) on three days. 58. Review of the Medication Refrigerator Temperature Logs for 03/16 showed direction for staff to monitor the temperatures daily: - No temperature was recorded for 03/03/16, 03/07/16 and 03/10/16; - Temperature was recorded out of range on six of nine recorded days based on the temperature log range of 34-40 degree F with no intervention recorded; - Temperature was outside the Rhogam manufacturer's recommended temperature range of 36-46 degree F for seven of nine recorded days; and - Temperatures were recorded at or below freezing on four days. 59. During an interview upon the observation, Staff D stated that the temperature of the refrigerator should be checked daily. She was not aware that the refrigerator was not being checked daily or that the temperature had been out of range.	L1128		

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L1128	Continued From page 18 60. Review of the FDA/Consumer Product Safety Commission (CPSC) document titled, "FDA/CPSC Public Health Advisory - Hazards Associated with the Use of Electric Heating Pads", dated 12/12/95, showed: - The FDA and CPSC have received many reports of injury and death from burns, electric shock and fires associated with the use of electric heating pads. - An electric heating pad can be dangerous for patients with decreased temperature sensation and patients taking medication for pain. - Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting. 61. FDA and CPSC recommend the following precautions be taken to avoid hazards associated with the use of electric heating pads: - Never [partial list]: * Use on a person who has skin that is not sensitive to temperature changes (e.g. sedated or medicated for pain). * Use in an oxygen enriched environment or near equipment that stores or emits oxygen. 62. Observation on 03/14/16 at 2:00 PM in the pre-post area showed: - 10 reclining chairs with electric heating pads placed across the backs; - The heating pads were labeled for Household Use Only. During an interview upon the observation, Staff D stated that: - The heating pads were used for patient comfort after their procedure. - She was not aware the facility should not use	L1128		

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L1128	Continued From page 19 electric heating pads specified for household use for patient care.	L1128		
L1137	19 CSR 30-30.060(1)(B)(13) A personnel record shall be maintained A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs). This regulation is not met as evidenced by: Based on state statute review, policy review, record review, and interview, the facility failed to: - Perform criminal background checks (CBCs - completion of an inquiry to the Highway Patrol for criminal records available for disclosure to a provider, to determine an individual's criminal history) prior to hire for four (Staff D, O, P, and Q) of thirteen personnel files reviewed; - Perform employee disqualification list (EDL) inquiries (to determine if the employee was placed on the EDL list maintained by the Department of Health and Senior Services, regarding employment eligibility) prior to hire for three (Staff O, P, and Q) of thirteen employees personnel files reviewed; - Provide ongoing staff education regarding infection control for five (Staff E, G, I, O, and P) of thirteen personnel files reviewed; and - Ensure orientation was completed for two (Staff O and P) of thirteen personnel files reviewed. The Abortion Facility does an average of 424 cases per month. On the first day of the survey, there were 32 cases.	L1137		

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L1137	Continued From page 20 Findings included: 1. Review of the Missouri Statute Chapter 660, showed that CBCs were required by any provider pursuant to Section 660.317.1 (that included facilities licensed under Chapter 197 - Ambulatory Surgical Centers and Abortion Facilities) prior to allowing any person who had been hired as a full-time, part-time or temporary position, to have contact with any patient. 2. Review of the Missouri Statute Chapter 660, showed that EDL checks were required by any provider pursuant to Section 660.315 (that included facilities licensed under Chapter 197 - Ambulatory Surgical Centers and Abortion Facilities) to determine employment eligibility. 3. Review of the facility's document titled, "Employee Manual," dated 07/13, showed: - The Vice President (VP) of Human Resources would be responsible for performing all "background checks" that are applicable under Federal, State and Planned Parenthood of America laws and requirements; and - All candidates prior to hire will have a criminal background check and Employee Disqualification List search completed prior to hire, per the Missouri Revised Statutes Chapter 660, Section 317. 4. Review of the personnel file for Staff D, Director of Surgical Services, showed she was hired 02/23/15. The facility failed to complete the CBC prior to hire to ensure employment eligibility. 5. Review of the personnel file for Staff O, Volunteer, showed she did not have a personnel	L1137		

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L1137	Continued From page 21 file. The facility failed to complete a CBC, and an EDL search, to ensure employment eligibility, which included volunteers, prior to having contact with any patients. 6. Review of the personnel file for Staff P, Volunteer for the Practicum Program, showed she was hired 08/06/2006. The facility failed to complete a CBC, and an EDL search, to ensure employment eligibility, which included volunteers, prior to having contact with any patients. 7. Review of the personnel file for Staff Q, Volunteer, showed no documentation of her start date. The facility failed to complete a CBC, and an EDL search, to ensure employment eligibility, which included volunteers, prior to having contact with any patients. 8. During an interview on 03/15/16 at 11:35 AM, Staff L, VP of Human Resources, stated that she had been out of the office on surgical leave, which caused Staff D's CBC to have been completed after her hire date. 9. During an interview on 03/15/16 at 1:30 PM, Staff B, Registered Nurse, VP of Patient Services, stated that: - They had not kept personnel files on volunteers that started working at Planned Parenthood until five years ago; - They had not performed EDL's on volunteers that started more than five years ago; - Staff O had been a volunteer for more than 30 years; and - They had not completed a CBC or an EDL on Staff O. 10. During an interview on 03/15/16 at 3:10 PM,	L1137		

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L1137	Continued From page 22 staff L stated that: - They started completing EDL's on volunteers a few years ago; - They had not completed CBCs on volunteers because of the cost; - She needed to make personnel files on all volunteers to include CBCs and EDL searches; and - She agreed the CBCs and EDL's had not been completed on Staff O, P, and Q. 11. Review of the facility's document titled, "Infection Prevention Manual" dated 10/14/14, showed: - The Infection Prevention Program referenced the Centers for Disease Control and Prevention guidelines; - Training included infection prevention education and training for all staff that have the potential for exposure to patients and/or infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. This includes persons not directly involved in patient care (e.g., volunteers, non-medical staff, contractual staff, and housekeeping) but potentially exposed to infectious agents that can be transmitted to and from staff and patients; and - Training is provided as part of staff departmental orientation and repeated regularly, at least annually, or as needed with new procedures or systems focusing on staff and patient safety. 12. Review of the personnel files for Staff E, Licensed Clinical Social Worker, and Staff I, Sonographer, showed the last infection control training date was 11/11/14.	L1137		

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L1137	Continued From page 23 13. Review of the personnel file for Staff G, Lead Health Center Assistant, showed the last infection control training date was 09/25/14. 14. Review of the personnel file for Staff O showed she did not have a personnel file and there was no documentation to show she had infection control training. 15. Review of the personnel file for Staff P showed she was hired 09/05/2006. There was no documentation to show she had infection control training. 16. Review of the personnel file for Staff Q showed the last infection control training date was 08/14. 17. During an interview on 03/15/16 at 1:30 PM, Staff B stated that Staff O had been a volunteer for more than 30 years and had not completed infection control training. 18. During an interview on 03/16/16 at 12:45 PM, Staff C, Director of Quality and Compliance, stated that: - The facility held an infection control training class on 01/28/16; and - Staff E, Staff G, and Staff I did not attend the class. 19. Review of the facility's document titled, "Employee Manual," dated 07/13, showed all employees and volunteers are required to sign an Annual Privacy Statement in compliance with this policy and the federal Health Insurance Portability and Accountability Act (HIPPA). 20. Review of the facility's undated online	L1137		

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L1137	Continued From page 24 orientation and training document titled, "Getting started with the Center for Affiliated Learning (CAL)," showed: - CAL videos are to be watched by each full-time, part-time, and per diem employee, and volunteers; and - CAL videos included: * Intimate Partner Violence 1, 2, and 3; * Blood Borne Pathogens; * Sterile Technique; * Cleaning and Disinfection; * Talking about Abortion 1, 2, and 3; * Orientation to the Abortion Pill 1, 2, and 3; and * Health Care Assistant 1 and 2. 21. Review of the personnel file for Staff O showed she did not have a personnel file. The facility failed to provide documentation of orientation or a signed confidentiality statement. 22. Review of the personnel file for Staff P showed she was hired on 09/05/06. The facility failed to provide documentation of orientation or a signed confidentiality statement. 23. During an interview on 03/15/16 at 2:50 PM, Staff D stated that anyone they chose to volunteer at the facility would complete the CAL training, the same way newly hired employees had done.	L1137		
L1153	19 CSR 30-30.060(2)(C) The medical record shall contain The medical record shall contain-a unique identifying record number, patient identifying information, name of physician, diagnosis, medical history and physical examination record, laboratory reports, tissue reports, anesthesia,	L1153		

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L1153	Continued From page 25 allergies/drug reactions, physician's orders, clinical notes, counseling notes, patient consent form, medication administration records and discharge summary. All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure medication orders were timed, dated and signed by the ordering practitioner and medications administered to the patient were documented including dose, time, date, and signed by the person making the entry for 11 (#1, #2, #3, #4, #5, #6, #9, #10, #17, #19, and #20) of 13 patients' medical records reviewed. The Ambulatory Surgical Center does an average of 424 cases per month. On the first day of the survey, there were 32 cases. Findings included: 1. Review of the facility's policy titled, "Medical Records Documentation, and Reporting Requirements," dated 06/14, showed: - Documentation must be performed in accordance with accepted professional standards and any applicable laws/regulations. It must: *Be legible, factual, complete, concise and professional. *Be signed with the full name of the signer including credentials for licensed staff and titles for non-licensed staff. (The facility failed to give staff direction for documentation of pharmaceuticals to be timed, dated, and signed by the person making the entry.)	L1153		

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L1153	Continued From page 26 2. Review of the facility's document titled, "Registered Nurse (RN)/ Licensed Practical Nurse (LPN) Standing Orders," dated 06/19/13, showed: - RNs and LPNs may order and submit medication(s) in the electronic health record (EHR) per these standing orders. - Physician will review as part of patient care process. - All assessments, treatments and patient conditions must be fully documented in the patient record. (Note: The facility failed to include directions for completing the order set or require the standing orders to be timed, dated, and signed by the physician.) 3. Review of Patient #1's medical record for 01/30/16 showed: - Eight medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers (solution for fluid and electrolyte replacement) administered intravenously (IV- small catheter inserted into a vein for administering medication and fluid). - Five medications documented as administered by nursing staff with no dose, and not timed, dated or signed by the nurse. - A narrative note by Staff T, RN, documenting that Methergine (medication that increases uterine contractions) 0.2 milligram (mg, unit of measure) was administered at 4:46 PM; the patient was discharged from the facility at 12:55 PM. - A notation on the record that the document was electronically signed by Staff F, LPN, on 02/05/16 on behalf of Staff GG, Physician.	L1153		

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	MOA-0014	A. BUILDING: _____ B. WING _____	03/16/2016

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L1153	Continued From page 27 4. Review of Patient #2's medical record for 02/23/16 showed: - Five medication orders not timed, dated or signed by the physician. - Four medications documented as administered by nursing staff with no dose administered, and not timed, dated or signed by the nurse. - Provider: Staff DD, Physician, not dated, timed or electronically signed. Review of Patient #2's medical record for 02/24/16 showed: - Six medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff DD, not dated, timed or electronically signed. - Document generated by Staff S, Health Center Assistant. 5. Review of Patient #3's medical record for 03/11/16 showed: - Five medication orders not timed, dated or signed by the physician. - Four medications documented as administered by nursing staff with no dose administered, and not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff S. Review of Patient #3's medical record for 03/12/16 showed: - Seven medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Three medications documented as administered by nursing staff with no dose and	L1153		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1153	Continued From page 28 not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff T. 6. Review of Patient #4's medical record for 03/08/16 showed: - Five medication orders not timed, dated or signed by the physician. - Four medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider and document generated by Staff JJ, Physician, not dated, timed or electronically signed. Review of Patient #4's medical record for 03/09/16 showed: - Seven medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider and document generated by Staff JJ, not dated, timed or electronically signed. 7. Review of Patient #5's medical record for 02/12/16 showed: - Six medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Four medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff J, RN. 8. Review of Patient #6's medical record for	L1153		

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L1153	Continued From page 29 02/05/16 showed: - Four medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Two medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff R, Advanced Practice Registered Nurse (APRN), Lead Clinician. 9. Review of Patient #9's medical record for 01/06/16 showed: - Six medication orders not timed, dated or signed by the physician. - One medication with no dose documented, administered by a physician. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff JJ, not dated, timed or electronically signed. - Document generated by Staff S. 10. Review of Patient #10's medical record for 12/24/15 showed: - Seven medication orders not timed, dated or signed by the physician. - One medication with no dose documented, administered by a physician. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff JJ, not dated, timed or electronically signed. Review of Patient #10's medical record for 12/30/15 showed:	L1153		

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L1153	Continued From page 30 - Six medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Six medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff DD, not dated, timed or electronically signed. - Document generated by: Staff S. 11. Review of Patient #17's medical record for 02/27/16 showed "oral sedation" administered at 10:30 AM. Staff failed to document what medication was administered and signature of person who administered the medication. 12. Review of Patient #19's medical record for 06/19/15 showed no order for Lactate Ringers administered IV. During an interview on 03/16/16 at 1:25 PM, Staff JJ stated that there were standing orders to give IV fluid for dehydration. 13. Review of Patient #20's medical record for 07/10/15 showed three medications documented as administered by nursing staff but staff failed to time, date or sign. 14. During an interview on 03/15/16 at 8:30 AM, Staff R stated that: - There was not a place in the medical record for the nurse to document who administered the medication. - Medications were not associated with times in the EMR. - The facility had a set of pre-printed orders used by the nursing staff. - The pre-printed orders were not scanned into	L1153		

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L1153	Continued From page 31 the EMR. - The physician reviewed the entire record, including the orders. - A notation in the chart, "document generated by," with the physician's name is the equivalent of the physicians' signature. - The physician's signature was not dated or timed. 15. During an interview on 03/16/16 at 10:00 AM, Staff JJ stated that: - The medical staff had developed standing orders for the nursing staff to follow. - The standing orders included all medications that would be administered on a routine basis in the facility. - The standing orders were not signed off for each patient and were not scanned into the medical record. - The physicians reviewed the medical record and electronically signed off on the record. - The electronic medical record signature covered medication orders. 16. During an interview on 03/16/16 at 10:55 AM, Staff J stated that: - The nurses used a medical flow sheet that showed physician preference. - The nurses referred to a standing order sheet that was hung in a cabinet at the nurses' station. - The nurses used clinical judgement, the patient's pain level, and how big the patient was to determine dose when there was a dose option. 17. During an interview on 03/16/16 at 1:38 PM, Staff JJ stated that: - The standing orders populated into the medical record based on the gestational age, type of procedure the woman was having, and that	L1153		

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L1153	Continued From page 32 physician's preference. - The nurses may ask a physician if they needed to override the standing order or they could make their own clinical decision.	L1153		
L1165	19 CSR 30-30.060(3)(E) A patient shall be fully reactive A patient shall be fully reactive and her vital signs shall be stable before discharge from the facility. This regulation is not met as evidenced by: Based on policy review, record review and interview, the facility failed to ensure staff followed policy for monitoring the stability and vital signs of patients during recovery for nine (#2, #3, #4, #5, #6, #10, #17, #19, and #20) of 13 patients' medical records reviewed. The Ambulatory Surgical Center does an average of 424 cases per month. On the first day of the survey, there were 32 cases. Findings included: 1. Review of the facility's policy titled, "Recovery Area Care," dated 03/31/15, showed the following direction for staff: - 17.1.1 Sedated Clients: Must assess the following at initiation of recovery and then every 15 minutes during the recovery process until discharge: * Blood pressure (BP), respiratory rate, pulse, oxygen saturation; * Pain level; * Level of consciousness using the Aldrete Scoring System (a medical scoring system for the measurement of recovery after anesthesia which includes activity, respiration, consciousness, blood circulation and color); and	L1165		

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L1165	Continued From page 33 * Amount of bleeding, when applicable. - 17.1.2 Non-sedated clients: Must access the following at initiation of recovery and then every 15 minutes during the recovery process until discharge: * BP, respiratory rate, pulse (a minimum of 2 sets); * Pain level; and * Amount of bleeding, if applicable. - 17.2.a. Aldrete Scoring System: The client is rated a score between 0 - 2 on the following: * Activity level; * Respirations; * Circulation (BP) consciousness; and * Oxygen saturation as determined by pulse oximetry (device that measures oxygen saturation of the blood). 2. Review of Patient #2's medical record for 02/24/16 showed: - Recovery vital signs were documented as taken at 12:34 PM, 12:40 PM, 1:10 PM, 2:00PM, and 2:30 PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 9, 30, 50, and 30 minutes. - An aldrete score was not documented for the recovery period until the patient was discharged. 3. Review of Patient #3's medical record for 03/12/16 showed: - Recovery vital signs were documented as taken at 11:26 AM, 11:40 AM, 11:55 AM, 12:20 PM, 12:45 PM, 1:00 PM, and 1:25 PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 14, 15, 25, 25, 15, and 15 minutes . - An aldrete score was not documented for the recovery period until the patient was discharged.	L1165		

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L1165	Continued From page 34 4. Review of Patient #4's medical record for 03/09/16 showed: - Recovery vital signs were documented as taken at 12:02 PM, 12:22 PM, 1:00 PM, 1:20 PM, 1:40 PM, 2:00 PM and 2:15 PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 20, 38, 20, 20, 20, and 15 minutes. - An aldrete score was not documented for the recovery period until the patient was discharged. 5. Review of Patient #5's medical record for 02/12/16 showed: - Recovery vital signs were documented as taken at 3:50 PM, 4:15 PM, 4:50 PM, 5:00PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 25, 35, and 10 minutes. - An aldrete score was not documented for the recovery period until the patient was discharged. - The patient was discharged at 5:25 PM with no discharge vital signs recorded. 6. Review of Patient #6's medical record for 02/01/16 showed: - An aldrete score was notdocumented for the recovery period until the patient was discharged. 7. Review of Patient #10's medical record for 12/30/15 showed: - An aldrete score was not documented for the recovery period until the patient was discharged. 8. Review of Patient #17's medical record for 02/27/16 showed: - The patient was discharged at 1:16 PM with no discharge vital signs recorded. The previous vital signs were recorded at 12:50 PM. - Vital signs were not taken every 15 minutes. - An aldrete score was not documented for the	L1165		

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L1165	Continued From page 35 recovery period until the patient was discharged. 9. Review of Patient #19's medical record from 06/19/15 showed: - An aldrete score was not documented for the recovery period until the patient was discharged. 10. Review of Patient #20's medical record from 07/10/15 showed: - An aldrete score was not documented for the recovery period until the patient was discharged. 11. During an interview on 03/15/16, Staff R, Advanced Practice Registered Nurse, Lead Clinician, stated that: - Vital signs were to be taken and documented every 15 minutes while the patient was in recovery. - Aldrete scores should be assessed and documented every 15 minutes with vital signs. - She was not aware there was not a place to document the Aldrete scores on the recovery record.	L1165		

Missouri Department of Health and Senior Services

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L 000	Initial Comments An onsite, unannounced state licensure survey to determine compliance with 19 CSR 30-30.050 through 19 CSR 30-30.070 for Abortion Facilities was conducted from 03/14/16 to 03/16/16. See below for findings:	L 000		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to: - Follow the manufacturer's instructions for cleaning two of two autoclaves (sterilizers); - Follow the manufacturer's instructions for biological testing (used to monitor steam sterilizers); - Have a procedure in place to prevent cross contamination and separation of contaminated instruments by space; - Follow the manufacturer's instructions for packaging instruments for sterilization;	L1128		

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128 (Findings #1-3)	1. <u>Sterilizers should be inspected and cleaned daily according to manufacturer's written instructions.</u> RHS OF PPSLR will contact manufacture of autoclave (sterilizer) to determine appropriate product to address the discoloration. RHS OF PPSLR currently uses chamber brite and will continue to evaluate current staff utilization of this product to disinfect the autoclave.	4/15/16 4/15/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education.	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #4-7)	2. <u>Sterilizers maintenance should be documented timely and appropriately</u> Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include mention of performing a biological indicator with every load and containing a supervisory review. Conduct staff review of training updated Sterilization Room Humidity, Temperature and Autoclave maintenance Log and on appropriate and timely documentation of sterilizer maintenance and inclusion of "out of service" notation when equipment is not in-service.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Staff training will be conducted on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
				Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #8-12)	3. <u>Ensure biological indicators are utilized according to manufacturer's written instructions and documentation is appropriate.</u> Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include every load performance of biological indicator with every load and mention of supervisory review. Revise existing policy titled: Spore Testing Biological Indicator to reflect the requirement to perform a biological indicator with every load and document this in our maintenance log.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #13-15)	4. <u>Ensure procedure is in place to prevent cross-contamination and separation of dirty instruments</u> PPLSR updated current process to ensure that functional areas are physically separated (e.g. closure of pass through window) during phases of reprocessing. RHS OF PPSLR shall revise existing monthly site review to include specific criteria for decontamination & sterilization areas/process. Staff in-service on these revised processes to ensure full	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	dissemination of information.			Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #16-21)	5. <u>Follow manufacture's instruction for packaging of sterilized instruments</u> RHS OF PPSLR-RHS will purchase individualize instrument sterile peel packs, provide training to staff on the proper use of the individualized peel packs as indicated by the manufacture it relates to closure of package .	4/30/16	Director of Surgical Services; and Coordinator of Quality/ Training	Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on the manufacturer's instructions for the sterilization peel packs.	
L1128 (Findings #26)	6. <u>Restriction of multi-dose vials to centralized medication area from procedure room</u>. Revise existing PPSLR Policy titled Pharmaceutical Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for multi-dose vial usage. -Staff training for Pharmaceutical Services Policy to include: 1. Revised procedure for restricted medication area for multi-dose medications 2. Procedural review of usage, storage & discarding of multi-dose medications and controlled substance inventory management	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and RHS Nurse Practitioner	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Practitioner. Staff sign-in attendance sheet will be submitted as evidence.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128 (Findings #27-29)	7. <u>Restriction of single -dose vials to single patient use medication area from procedure room</u> Revise existing PPSLR Policy titled Pharmaceutical Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for multi-dose vial usage.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and RHS Nurse Practitioner	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Nurse Practitioner. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #34-45)	8. <u>Ensure clean, free from dust surfaces of equipment, drawers, shelves and other horizontal surfaces</u> Increase service areas and frequency of environmental cleaning performed by the environmental service technician (EVS tech). Provide training for EVS Tech on the updated span of areas to be cleaned and frequency. Update existing RHS audit checklist to include "removal of corrugated boxes in all patient care/storage areas".	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	Staff training on updated processes: environmental cleaning areas/frequency and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings 46-49)	9. <u>Ensure expired supplies not available for patient use</u> RHS or PPSLR shall conduct staff in service on: 1. Expired inventory management, 2. Revisions to existing weekly audit tool to reflect a daily and location specific tool (e.g. ultrasound and	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training	Staff training on updated processes: expectations and policy on expired inventory management and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	lab will have a daily audit tool).		and Director of Quality Training, and Education	Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #50-54)	10. <u>Ensure glucometer is approved by manufacturer for multi-clinical use</u> RHS OF PPSLR will purchase new multi-use glucometers. Training of staff on the approved manufacture's instruction for daily cleaning and disinfection.	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and RHS Nurse Practitioner	Staff training on updated processes: understanding and use of multi-use glucometer will be conducted by Nurse and Training Coordinator, RHS Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings 55-59)	11. <u>Ensure medication refrigerator temperatures are maintained</u> Modify existing policy titled: "Laboratory Refrigerator" to include range, action and re-check. Retrain staff on updated policy: Laboratory Refrigerator to include actionable steps when findings are out of appropriate range to be in accordance with manufacture's recommendations. Update the current RHS of PPSLR refrigerator Temperature Log.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	Staff training on updated processes: ensuring proper and accurate documentation or medication refrigerator and review of updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1128	12. <u>Ensure use of heating electrical devices is aligned with FDA/CRSC Public Health Advisory Guidelines</u> PPSLR-RHS will institute the use of a new product: Disposable heating packs in lieu electrical heating pads. Training of staff on the manufacturer's instructions for use of	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and	Staff training on updated processes: use of disposable heating packs will be conducted by Nurse and Training Coordinator, RHS Lead Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	the disposable heating packs.		RHS Lead Nurse Practitioner	submitted as evidence.	
L1137 (Findings #1,4-9)	1. Ensure criminal background checks are performed consistently. All RHS of PPSLR final candidates for employment and volunteer positions will have criminal background checks performed prior to employment offer. New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that criminal background checks have been performed	4/30/16	Vice President of Human Resources and Compliance	VP of HR shall ensure that the completions of criminal background checks are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity.	
L1137 (Findings #2,6-7,6)	2. Ensure employee disqualification list inquiries are consistently conducted. All RHS of PPSLR final candidates for employment and volunteer positions will have disqualification list inquiries checks performed prior to employment offer. New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that disqualification list inquiries checks have been performed.	4/30/16	Vice President of Human Resources and Compliance	VP of HR shall ensure that the completions of criminal background checks are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity.	
L1137 (Findings #11-19)	3. Ensure that ongoing staff education regarding infection control is consistently performed and documented. RHS of PPSLR shall review staff files to ensure that departmental training (e.g. infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. infection control). Quality /Training Coordinator shall ensure the documentation is provided in employee/volunteer HR file.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
				Vice President of Human Resources and Compliance will perform yearly audits on RHS of PPSLR on employee/volunteer files to ensure completion of yearly infection control training.	
L1137 (Findings #20-22)	4. <u>Ensure orientation is consistently completed and documented.</u> RHS of PPSLR shall review staff files to ensure that departmental training (.e.g. infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. infection control). Quality /Training Coordinator shall ensure the documentation is provided in employee/volunteer HR file. Vice President of Human Resources and Compliance will perform quarterly audits on RHS of PPSLR new employee/volunteer files to ensure completion of orientation training.	
L1153 (Findings #1 -17)	1. <u>Ensure medication orders are timed, dated and signed by ordering practitioner.</u> Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering practitioners and medications administrated to the patient are documented including dose, time and date and signed by the person administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated,	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Medical Director will provide training for	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	signed by the ordering practitioner and all medications administered to the patient are documented including date, time and initials of nurse who is administering medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives. RHS of PPSLR shall train staff and ordering physicians on the updated policy.			ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	
L1153 (Findings #1 -17)	2. <u>Ensure medication administered to patient are documented including dose, time timed, dated and signed by ordering practitioner.</u> Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives. Plan to train staff on the updated policy.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1153 (Findings 1-17)	3. <u>Ensure medical record documentation clearly provide staff direction for documentation and clinical judgement of pharmaceuticals to be timed, dated and signed by the person making the entry.</u> Updated existing PPSLR Policy titled: "Pharmaceutical Services" to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. Revised existing RHS-PPSLR Standing orders to include specific dosing ranges and pain levels associate with each pain level dosing. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	
L1165 (Findings #1-11)	1. <u>Ensure policy for monitoring the stability and vital signs of patients during recovery is consistently adhered to and documented.</u> Update existing Pre-op &Post-op Patient Documentation from to include documentation of Aldrete Scoring System. Retraining of staff on RHS of PPSLR Recovery Area Care	4/15/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct random daily audits of 5 patient charts per week for 4 weeks.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	Policy and updated Pre-op &Post-op Patient Documentation form.		and VP of Patient Services.	-Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Staff training will be conducted by Lead Nurse Practitioner , Nursing and Training Coordinator and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128 (Findings #1-3)	1. <u>Sterilizers should be inspected and cleaned daily according to manufacturer's written instructions.</u> RHS OF PPSLR will contact manufacture of autoclave (sterilizer) to determine appropriate product to address the discoloration. RHS OF PPSLR currently uses chamber brite and will continue to evaluate current staff utilization of this product to disinfect the autoclave.	4/15/16 4/15/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education.	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #4-7)	2. <u>Sterilizers maintenance should be documented timely and appropriately</u> Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include mention of performing a biological indicator with every load and containing a supervisory review. Conduct staff review of training updated Sterilization Room Humidity, Temperature and Autoclave maintenance Log and on appropriate and timely documentation of sterilizer maintenance and inclusion of "out of service" notation when equipment is not in service.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Staff training will be conducted on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log.	

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				Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #8-12)	3. <u>Ensure biological indicators are utilized according to manufacturer's written instructions and documentation is appropriate.</u> Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include every load performance of biological indicator with every load and mention of supervisory review. Revise existing Clinical Area Procedure Manual to reflect the requirement to perform a biological indicator with every load and document this in our maintenance log. Revise existing policy titled: Spore Testing Biological Indicator to reflect the requirement to perform a biological indicator with every load and document this in our maintenance log.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #13-15)	4. <u>Ensure procedure is in place to prevent cross-contamination and separation of dirty instruments</u> PPLSR updated current process to ensure that functional areas are physically separated (e.g. closure of pass through window) during phases of reprocessing. RHS OF PPSLR shall revise existing monthly site review to include specific criteria for decontamination & sterilization areas/process. Staff in-service on these revised processes to ensure full	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan.	

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	dissemination of information.			Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #16-21)	5. <u>Follow manufacture's instruction for packaging of sterilized instruments</u> RHS OF PPSLR-RHS will purchase individualize instrument sterile peel packs, provide training to staff on the proper use of the individualized peel packs as indicated by the manufacture it relates to closure of package .	4/30/16	Director of Surgical Services; and Coordinator of Quality/ Training	Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on the manufacturer's instructions for the sterilization peel packs. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #26)	6. <u>Restriction of multi-dose vials to centralized medication area from procedure room</u>. Revise existing PPSLR Policy titled Pharmaceutical Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for multi-dose vial usage. -Staff training for Pharmaceutical Services Policy to include: 1. Revised procedure for restricted medication area for multi-dose medications 2. Procedural review of usage, storage & discarding of multi-dose medications and controlled substance inventory management	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and RHS Nurse Practitioner	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Practitioner. Staff sign-in attendance sheet will be submitted as evidence.	

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L1128 (Findings #27-29)	7. Restriction of single -dose vials to single patient use medication area from procedure room Revise existing PPSLR Policy titled Pharmaceutical Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for multi-dose vial usage.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and RHS Nurse Practitioner	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Nurse Practitioner. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #34-45)	8. Ensure clean, free from dust surfaces of equipment, drawers, shelves and other horizontal surfaces Increase service areas and frequency of environmental cleaning performed by the environmental service technician (EVS tech). Provide training for EVS Tech on the updated span of areas to be cleaned and frequency. Update existing RHS audit checklist to include "removal of corrugated boxes in all patient care/storage areas".	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	Staff training on updated processes: environmental cleaning areas/frequency and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings 46-49)	9. Ensure expired supplies not available for patient use RHS of PPSLR shall conduct staff in service on: 1. Expired inventory management, 2. Revisions to existing weekly audit tool to reflect a daily and location specific tool (e.g. ultrasound and	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training	Staff training on updated processes: expectations and policy on expired inventory management and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	lab will have a daily audit tool).		and Director of Quality Training, and Education	Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #50-54)	10. <u>Ensure glucometer is approved by manufacturer for multi-clinical use</u> RHS OF PPSLR will purchase new multi-use glucometers. Training of staff on the approved manufacture's instruction for daily cleaning and disinfection.	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and RHS Nurse Practitioner	Staff training on updated processes: understanding and use of multi-use glucometer will be conducted by Nurse and Training Coordinator, RHS Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings 55-59)	11. <u>Ensure medication refrigerator temperatures are maintained</u> Modify existing policy titled: "Laboratory Refrigerator" to include range, action and re-check. Retrain staff on updated policy: Laboratory Refrigerator to include actionable steps when findings are out of appropriate range to be in accordance with manufacture's recommendations. Update the current RHS of PPSLR refrigerator Temperature Log.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	Staff training on updated processes: ensuring proper and accurate documentation or medication refrigerator and review of updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1128	12. <u>Ensure use of heating electrical devices is aligned with FDA/CRSC Public Health Advisory Guidelines</u> PPSLR RHS will institute the use of a new product: Disposable heating packs in lieu electrical heating pads. Training of staff on the manufacturer's instructions for use of	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and	Staff training on updated processes: use of disposable heating packs will be conducted by Nurse and Training Coordinator, RHS Lead Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be	

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	the disposable heating packs.		RHS Lead Nurse Practitioner	submitted as evidence.	
L1137 (Findings #1,4-9)	1. Ensure criminal background checks are performed consistently. All RHS of PPSLR final candidates for employment and volunteer positions will have criminal background checks performed prior to employment offer. New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that criminal background checks have been performed	4/30/16	Vice President of Human Resources and Compliance	VP of HR shall ensure that the completions of criminal background checks are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity. New Hire Checklist audit will be conducted within the 1st week of every month by VP of HR and Compliance to ensure compliance .	
L1137 (Findings #2,6-7,6)	2. Ensure employee disqualification list inquiries are consistently conducted. All RHS of PPSLR final candidates for employment and volunteer positions will have disqualification list inquiries checks performed prior to employment offer. New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that disqualification list inquiries checks have been performed.	4/30/16	Vice President of Human Resources and Compliance	VP of HR shall ensure that the completions of criminal background checks are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity. New Hire Checklist audit will be conducted within the 1st week of every month by VP of HR and Compliance to ensure compliance .	
L1137 (Findings #11-19)	3. Ensure that ongoing staff education regarding infection control is consistently performed and documented. RHS of PPSLR shall review staff files to ensure that departmental training (e.g. annual infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. annual infection control). Quality /Training Coordinator shall ensure the documentation is provided in employee/volunteer HR file.	

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				Vice President of Human Resources and Compliance will perform yearly audits on RHS of PPSLR on employee/volunteer files to ensure completion of yearly infection control training.	
L1137 (Findings #20-22)	4. <u>Ensure orientation is consistently completed and documented.</u> RHS of PPSLR shall review staff files to ensure that departmental training (.e.g. infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. infection control). Quality /Training Coordinator shall ensure the documentation is provided in employee/volunteer HR file. Vice President of Human Resources and Compliance will perform quarterly audits on RHS of PPSLR new employee/volunteer files to ensure completion of orientation training.	
L1153 (Findings #1 -17)	1. <u>Ensure medication orders are timed, dated and signed by ordering practitioner.</u> Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering practitioners and medications administrated to the patient are documented including dose, time and date and signed by the person administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated,	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management)	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	signed by the ordering practitioner and all medications administered to the patient are documented including date, time and initials of nurse who is administering medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives. RHS of PPSLR shall train staff and ordering physicians on the updated policy.			Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	
L1153 (Findings #1 -17)	2. <u>Ensure medication administered to patient are documented including dose, time timed, dated and signed by ordering practitioner.</u> Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	Plan to train staff on the updated policy.			Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	
L1153 (Findings 1-17)	3. <u>Ensure medical record documentation clearly provide staff direction for documentation and clinical judgement of pharmaceuticals to be timed, dated and signed by the person making the entry.</u> Updated existing PPSLR Policy titled: "Pharmaceutical Services" to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. Revised existing RHS-PPSLR Standing orders to include specific dosing ranges and pain levels associate with each pain level dosing. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders"	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
				Staff sign-in attendance sheet will be submitted as evidence.	
L1165 (Findings #1-11)	1. <u>Ensure policy for monitoring the stability and vital signs of patients during recovery is consistently adhered to and documented.</u> Update existing Pre-op &Post-op Patient Documentation from to include documentation of Aldrete Scoring System. Retraining of staff on RHS of PPSLR Recovery Area Care Policy and updated Pre-op &Post-op Patient Documentation form.	4/15/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education and VP of Patient Services.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. --Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting . Staff training will be conducted by Lead Nurse Practitioner , Nursing and Training Coordinator and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

April 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***PoC Rejection***

Dear Mary Kogut:

On April 7, 2016 our Bureau received your Plan of Correction as a result of a Licensure Survey conducted March 16, 2016. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

L1128 -

- #1-Will the autoclaves be professionally cleaned to return the chambers to a satisfactory condition? Please include any re-education of staff on following manufacturer's instructions. Please confirm and provide documentation.
- #3-Please include the document referenced in the plan of correction titled, "Spore Testing Biological Indicator," and include staff education on following manufacturer's instructions.
- #5-Are all formerly processed instruments done incorrectly being reprocessed? Please confirm and provide documentation.
- #6-If available, include the document referenced in the plan of correction titled, "Pharmaceutical Services."
- #7-Training should be specific to single-dose vials (this was copied from #6's multi-dose vials). If available, include the document referenced in the plan of correction titled, "Pharmaceutical Services."
- Glucometer-When the new multi-patient use glucometers are purchased, will the facility update their current policy to include instructions for cleaning **and** disinfecting the glucometer or to follow manufacturer's guidelines?

L1137-

- CBC's – The criminal background checks need to be completed for the three volunteers currently staffed at the facility.
- EDL's – Please include a plan for periodic EDL verifications. Also, the EDL's need to be completed for the three volunteers currently staffed at the facility. The plan of correction does not mention monitoring for EDL verification compliance (it says CBC in the EDL plan of correction area).

L1153 -
Please include the documents referenced in the plan of correction titled, "Pharmaceutical Services" (also referenced in L1128 #6), "RHS Patient Orders", and "RHS-PPSLR Standing Orders."

L1165 -
Please include the document referenced in the plan of correction titled, "Pre-op & Post-op Patient Documentation."

Please submit a revised Plan of Correction with the above mentioned information within five (5) calendar days from the receipt of this notice via email to BAC@health.mo.gov or fax to (573) 751-6158 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083 Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

April 27, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***2nd PoC Rejection***

Dear Mary Kogut:

On April 12, 2016 our Bureau received your Plan of Correction as a result of a Licensure Survey conducted March 15, 2016. Your Plan of Correction is unacceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

L1128 –
#3 – The document titled, "ARMS Infection Control Manual," continues to require a minimum weekly spore test, or possibly daily. The manufacturer's instructions for the Attest show they are to be used with every load. Your ARMS Infection Control Manual references CDC's guidance for oral health. Your abortion facility does not provide dental services. The plan of correction includes multiple nationally-recognized standards of which your facility does not follow (Example: American Dental Association). Per ANSI/AAMI ST79, "All BIs should be used in accordance with the BI manufacturer's written instructions." Either the Infection Control Manual needs changed to reflect the manufacturer's instructions or a different product must be used to accommodate your policy of a weekly or daily spore test. We would encourage you to select a nationally-recognized standard that is relevant to surgical services in general, not dental.

Please submit a revised Plan of Correction with the above mentioned information within five (5) calendar days from the receipt of this notice via email to BAC@health.mo.gov or fax to (573) 751-6158 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128 (Findings #1-3)	1. <u>Sterilizers should be inspected and cleaned daily according to manufacturer's written instructions.</u> RHS OF PPSLR will contact manufacture of autoclave (sterilizer) to determine appropriate product to address the discoloration. Manufacture will perform the appropriate professional cleaning. RHS OF PPSLR currently uses chamber brite and will continue to evaluate current staff utilization of this product to disinfect the autoclave.	4/15/16 4/15/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education.	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	F3: Picture of the cleaned autoclave machines as of 4/14/16. F3: Training Material provided to staff and staff sign-in sheet.
L1128 (Findings #4-7)	2. <u>Sterilizers maintenance should be documented timely and appropriately</u> Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include mention of performing a biological indicator with every load and containing a supervisory review. Conduct staff review of training updated Sterilization Room Humidity, Temperature and Autoclave maintenance Log and on appropriate and timely documentation of sterilizer maintenance and inclusion of "out of service" notation when equipment is not in service	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Staff training will be conducted on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log.	

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				Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #8-12)	3. <u>Ensure biological indicators are utilized according to manufacturer's written instructions and documentation is appropriate.</u> Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include every load performance of biological indicator with every load and mention of supervisory review. Revise existing Clinical Area Procedure Manual to reflect the requirement to perform a biological indicator with every load and document this in our maintenance log. Revise existing policy titled: Spore Testing Biological Indicator to reflect the requirement to perform a biological indicator with every load and document this in our maintenance log.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	F1: PPFA-ARM's Infection Prevention Manual "Spore Testing Biological Indicator" Policy. F2: Vendor Recommendations and Staff Sign-in Sheet
L1128 (Findings #13-15)	4. <u>Ensure procedure is in place to prevent cross-contamination and separation of dirty instruments</u> PPLSR updated current process to ensure that functional areas are physically separated (e.g. closure of pass through window) during phases of reprocessing. RHS OF PPSLR shall revise existing monthly site review to include specific criteria for decontamination & sterilization areas/process. Staff in-service on these revised processes to ensure full	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	dissemination of information.			Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #16-21)	5. <u>Follow manufacture's instruction for packaging of sterilized instruments</u> RHS OF PPSLR-RHS will purchase individualize instrument sterile peel packs, provide training to staff on the proper use of the individualized peel packs as indicated by the manufacture it relates to closure of package . RHS of PPSLR will reprocess all instruments formerly processed as the staff retraining is performed.	4/30/16	Director of Surgical Services; and Coordinator of Quality/ Training	Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on the manufacturer's instructions for the sterilization peel packs. Staff sign-in attendance sheet will be submitted as evidence.	F1: PPFA-ARM's Infection Prevention Manual "Packaging Instructions" Policy. F2: Staff Re-training and sign-in sheet for packaging of sterilized instruments.
L1128 (Findings #26)	6. <u>Restriction of multi-dose vials to centralized medication area from procedure room</u>. Revise existing PPSLR Policy titled Pharmaceutical Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for multi-dose vial usage.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and RHS Nurse Practitioner	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Practitioner. Staff sign-in attendance sheet will be submitted as evidence.	F1: Pharmaceutical Services Policy.

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	-Staff training for Pharmaceutical Services Policy to include: 1. Revised procedure for restricted medication area for multi-dose medications 2. Procedural review of usage, storage & discarding of multi-dose medications and controlled substance inventory management				
L1128 (Findings #27-29)	7. <u>Restriction of single -dose vials to single patient use medication area from procedure room</u> Revise existing PPSLR Policy titled Pharmaceutical Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for single-dose vial usage.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and RHS Nurse Practitioner	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Nurse Practitioner. Staff sign-in attendance sheet will be submitted as evidence.	F1: Pharmaceutical Services Policy.
L1128 (Findings #34-45)	8. <u>Ensure clean, free from dust surfaces of equipment, drawers, shelves and other horizontal surfaces</u> Increase service areas and frequency of environmental cleaning performed by the environmental service technician (EVS tech). Provide training for EVS Tech on the updated span of areas to be cleaned and frequency. Update existing RHS audit checklist to include "removal of corrugated boxes in all patient care/storage areas".	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	Staff training on updated processes: environmental cleaning areas/frequency and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator. Staff sign-in attendance sheet will be submitted as evidence.	

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L1128 (Findings 46-49)	9. <u>Ensure expired supplies not available for patient use</u> RHS of PPSLR shall conduct staff in service on: 1. Expired inventory management, 2. Revisions to existing weekly audit tool to reflect a daily and location specific tool (e.g. ultrasound and lab will have a daily audit tool).	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	Staff training on updated processes: expectations and policy on expired inventory management and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #50-54)	10. <u>Ensure glucometer is approved by manufacturer for multi-clinical use</u> RHS OF PPSLR will purchase new multi-use glucometers. Training of staff on the approved manufacture's instruction for daily cleaning and disinfection. RHS of PPSLR shall update current policy to include the manufacture's recommendations for cleaning and disinfecting the new multi-use glucometers.	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and RHS Nurse Practitioner	Staff training on updated processes: understanding and use of multi-use glucometer will be conducted by Nurse and Training Coordinator, RHS Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings 55-59)	11. <u>Ensure medication refrigerator temperatures are maintained</u> Modify existing policy titled: "Laboratory Refrigerator" to include range, action and re-check. Retrain staff on updated policy: Laboratory Refrigerator to include actionable steps when findings are out of appropriate range to be in accordance with manufacture's	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and	Staff training on updated processes: ensuring proper and accurate documentation or medication refrigerator and review of updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator and Director of Surgical Services.	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	recommendations. Update the current RHS of PPSLR refrigerator Temperature Log.		Director of Quality Training, and Education	Staff sign-in attendance sheet will be submitted as evidence.	
L1128	12. <u>Ensure use of heating electrical devices is aligned with FDA/CPSC Public Health Advisory Guidelines</u> PPSLR-RHS will institute the use of a new product: Disposable heating packs in lieu electrical heating pads. Training of staff on the manufacturer's instructions for use of the disposable heating packs.	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and RHS Lead Nurse Practitioner	Staff training on updated processes: use of disposable heating packs will be conducted by Nurse and Training Coordinator, RHS Lead Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1137 (Findings #1,4-9)	1. <u>Ensure criminal background checks are performed consistently.</u> All RHS of PPSLR final candidates for employment and volunteer positions will have criminal background checks performed prior to employment offer. New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that criminal background checks have been performed	4/30/16	Vice President of Human Resources and Compliance	VP of HR shall ensure that the completions of criminal background checks are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity. Existing volunteers currently staffed will receive a criminal background check by due date. New Hire Checklist audit will be conducted within the 1st week of every month by VP of HR and Compliance to ensure compliance .	
L1137 (Findings #2,6-7,6)	2. <u>Ensure employee disqualification list inquiries are consistently conducted.</u> All RHS of PPSLR final candidates for employment and volunteer positions will have disqualification list inquiries checks performed prior to employment offer.	4/30/16	Vice President of Human Resources and Compliance	VP of HR shall ensure that the completions of EDL are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity; the EDL shall be done quarterly thereafter by VP of HR. New Hire Checklist audit will be conducted	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that disqualification list inquiries checks have been performed.			within the 1st week of every month by VP of HR and Compliance to ensure compliance .	
L1137 (Findings #11-19)	3. <u>Ensure that ongoing staff education regarding infection control is consistently performed and documented.</u> RHS of PPSLR shall review staff files to ensure that departmental training (.e.g. annual infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. annual infection control). Quality /Training Coordinator shall ensure the documentation is provided in employee/volunteer HR file. Vice President of Human Resources and Compliance will perform yearly audits on RHS of PPSLR on employee/volunteer files to ensure completion of yearly infection control training.	
L1137 (Findings #20-22)	4. <u>Ensure orientation is consistently completed and documented.</u> RHS of PPSLR shall review staff files to ensure that departmental training (.e.g. infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. infection control). Quality /Training Coordinator shall ensure the documentation is provided in employee/volunteer HR file. Vice President of Human Resources and Compliance will perform quarterly audits on RHS of PPSLR new employee/volunteer files	

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
				to ensure completion of orientation training.	
L1153 (Findings #1 -17)	1. <u>Ensure medication orders are timed, dated and signed by ordering practitioner.</u> Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering practitioners and medications administrated to the patient are documented including dose, time and date and signed by the person administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering practitioner and all medications administered to the patient are documented including date, time and initials of nurse who is administering medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives. RHS of PPSLR shall train staff and ordering physicians on the updated policy.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	F1: Pharmaceutical Services Policy. F1: Pre-Printed Physician's Order Sheet F1: RHS of PPSLR Medication Administration Record(MAR)
L1153 (Findings #1 -17)	2. <u>Ensure medication administered to patient are documented including dose, time timed, dated and signed by ordering practitioner.</u> Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that	5/6/16	Director of Surgical Services and Lead NP and Director of Quality,	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient	F1: Pharmaceutical Services Policy.

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ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives. Plan to train staff on the updated policy.		Training and Education.	charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	F1: Pre-Printed Physician's Order Sheet F1: RHS of PPSLR Medication Administration Record(MAR)
L1153 (Findings 1-17)	3. <u>Ensure medical record documentation clearly provide staff direction for documentation and clinical judgement of pharmaceuticals to be timed, dated and signed by the person making the entry.</u> Updated existing PPSLR Policy titled: "Pharmaceutical Services" to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management)	F1: Pharmaceutical Services Policy. F1: Pre-Printed

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	Revised existing RHS-PPSLR Standing orders to include specific dosing ranges and pain levels associate with each pain level dosing. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives.			Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	Physician's Order Sheet F1: RHS of PPSLR Medication Administration Record(MAR)
L1165 (Findings #1-11)	1. <u>Ensure policy for monitoring the stability and vital signs of patients during recovery is consistently adhered to and documented.</u> Update existing Pre-op &Post-op Patient Documentation from to include documentation of Aldrete Scoring System. Retraining of staff on RHS of PPSLR Recovery Area Care Policy and updated Pre-op &Post-op Patient Documentation form.	4/15/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education and VP of Patient Services.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. --Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting . Staff training will be conducted by Lead Nurse Practitioner , Nursing and Training Coordinator and Director of Quality, Training and	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
				Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	

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Reproductive Health Services of Planned Parenthood of the St. Louis Region
Procedural Monitoring- Moderate Sedation Vital Sign Documentation

DATE: _____ PATIENT'S NAME: _____ DOB: _____ MRN: _____

Sedation Monitor:		***Procedure Assistant:***	
_____ Print Name/Signature	_____ Print Name/Signature	_____ Print Name/Signature	_____ Print Name/Signature

Parameter	Description of Client	Score
Activity Level	--Moves all extremities voluntarily/on command --Moves 2 extremities --Cannot move extremities	--2 --1 --0
Respirations	--Breathes deeply and coughs freely --Is dyspneic, with shallow, limited breathing --Is apneic	--2 --1 --0
Circulation (BP)	--Is 20mm Hg > preanesthetic level --Is 20 to 50mm hg > preanesthetic level --Is 50mm Hg > preanesthetic level	--2 --1 --0
Consciousness	--Is fully awake --Is arousable on calling --Is not responding	--2 --1 --0
Oxygen saturation as determined by pulse oximetry	--Has level >90% when breathing room air --Requires supplemental oxygen to maintain level >90% --Has level <90% with oxygen supplementation	--2 --1 --0

LEVEL OF CONSCIOUSNESS(LOC): 5-0
5 - AWAKE, ALERT, ORIENTED X3
4 - DROWSY, AROUSED WITH MINIMAL VERBAL STIMULI
3 - DROWSY, AROUSED WITH MODERATE VERBAL STIMULI
2 - DROWSY, AROUSED WITH TACTILE STIMULI
1 - REPONDS TO PAIN ONLY
0 - UNRESPONSIVE

PAIN: 0 – 10
NUMERIC INTENSITY SCALE

BLEEDING:0 – 4
0 – NONE
1 – SCANT
2 – LIGHT
3 – MOD.
4 - HEAVY

TIME	LOC	BP	HR	RR	O2%	☐Room Air ☐Mask L/Min____ ☐Nasal Cannula L/Min____	NOTES
							PRE - SEDATION

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Reproductive Health Services of Planned Parenthood of the St. Louis Region
Post-Procedural Monitoring – Vital Sign Documentation

DATE: _____ PATIENT'S NAME: _____ DOB_____ MRN: _____

Parameter	Description of Client	Score
Activity Level	–Moves all extremities voluntarily/on command –Moves 2 extremities –Cannot move extremities	–2 –1 –0
Respirations	–Breathes deeply and coughs freely –Is dyspneic, with shallow, limited breathing –Is apneic	–2 –1 –0
Circulation (BP	–Is 20mm Hg > preanesthetic level –Is 20 to 50mm hg > preanesthetic level –Is 50mm Hg > preanesthetic level	–2 –1 –0
Consciousness	–Is fully awake –Is arousable on calling –Is not responding	–2 –1 –0
Oxygen saturation as determined by pulse oximetry	–Has level >90% when breathing room air –Requires supplemental oxygen to maintain level >90% –Has level <90% with oxygen supplementation	–2 –1 –0

LEVEL OF CONSCIOUSNESS(LOC):5-0
5 - AWAKE, ALERT, ORIENTED X3
4 - DROWSY, AROUSED WITH MINIMAL VERBAL STIMULI
3 - DROWSY, AROUSED WITH MODERATE VERBAL STIMULI
2 - DROWSY, AROUSED WITH TACTILE STIMULI
1 - REPONDS TO PAIN ONLY
0 - UNRESPONSIVE

PAIN: 0 – 10
NUMERIC INTENSITY SCALE

BLEEDING (BLDG): 0 – 4
0 – NONE
1 – SCANT
2 – LIGHT
3 – MOD.
4 - HEAVY

ACTIVITY:
1 – Up to Bathroom w/o Assistance
2 – Up to Bathroom with Assistance
3 – Elevated patient feet in recliner
4 – Lowered head of recliner & Elevated patient feet in recliner

RECLINER #: **INTAKE TIME:** **DISCHARGE TIME:**

TIME	LOC	BP	HR	RR	O2%	PAIN	BLEEDING	ALDRETE SCORE	INTERVENTIONS / NOTES			STAFF INITIALS
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		
									HEATING PAD	MASSAGE		

Discharge Care Provided (Staff Must Initial to Indicate Completion of Services)

☐ Procedural Discharge Instructions Provided by:	☐ Birth Control Method Rx Verbal and Written Instructions Provided by: ☐ No Birth Control Method Desired by Patient.	☐ IV removed by:_____/_____ Name &Title / Time ☐ No IV provided to patient.				
_____/____ Staff Name / Time	_____/____ Staff Name / Time	_____/____ Staff Name / Time				

Discharge Nurse Signature_____/_____/_____
Signature/Date/Time

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E: RHS/Forms/Procedural Forms/Procedural_PostProcedural_2016

	A	B
1	Planned Parenthood®	
2		
3		
4	Care. No matter what.	
5	**Topic:**	**Training of use of New Biological Incubator & Sterilization Process**
6	**Speaker:**	Sharon Hawthorne
7	**Date:**	4/13/2016
8	**STAFF**	
9	Melissa Benton	M Benton
10	Carla Gardner	Carla Gardner
11	Cecelia Norman	C Norman
12	Sharon Hawthorne	S Hawthorne
13	Kelly McCutchen	
14	Jeshon Green	
15	Danelle Mozique	
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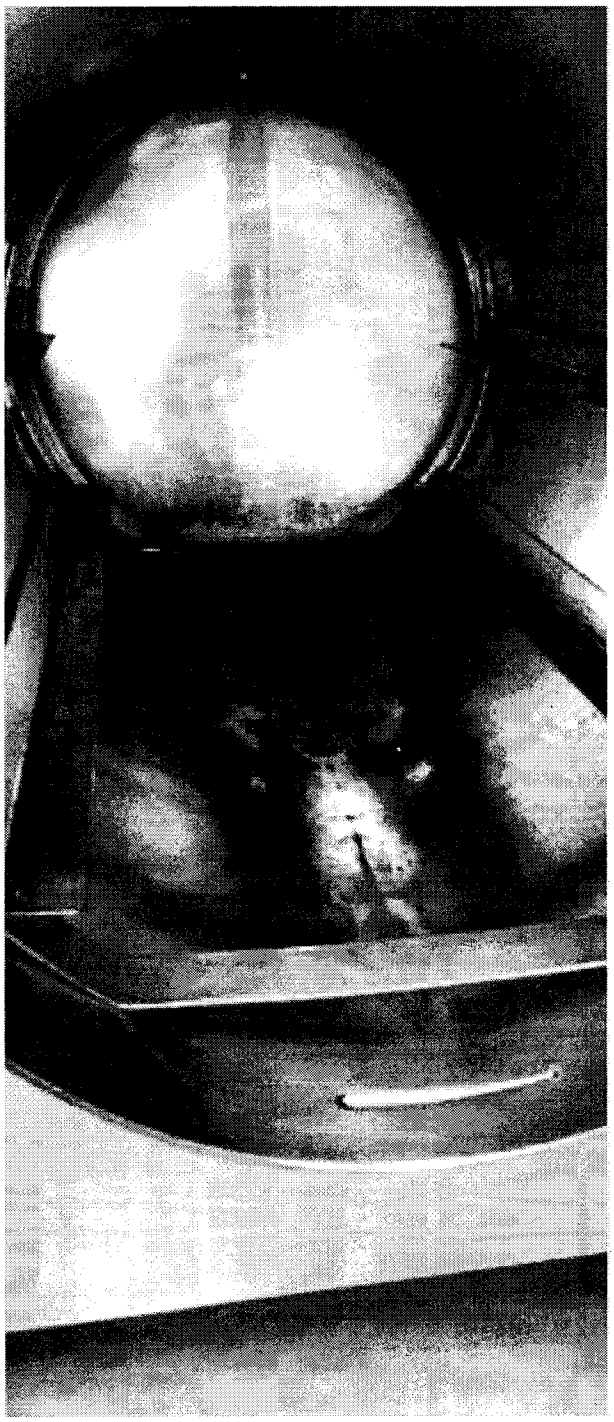
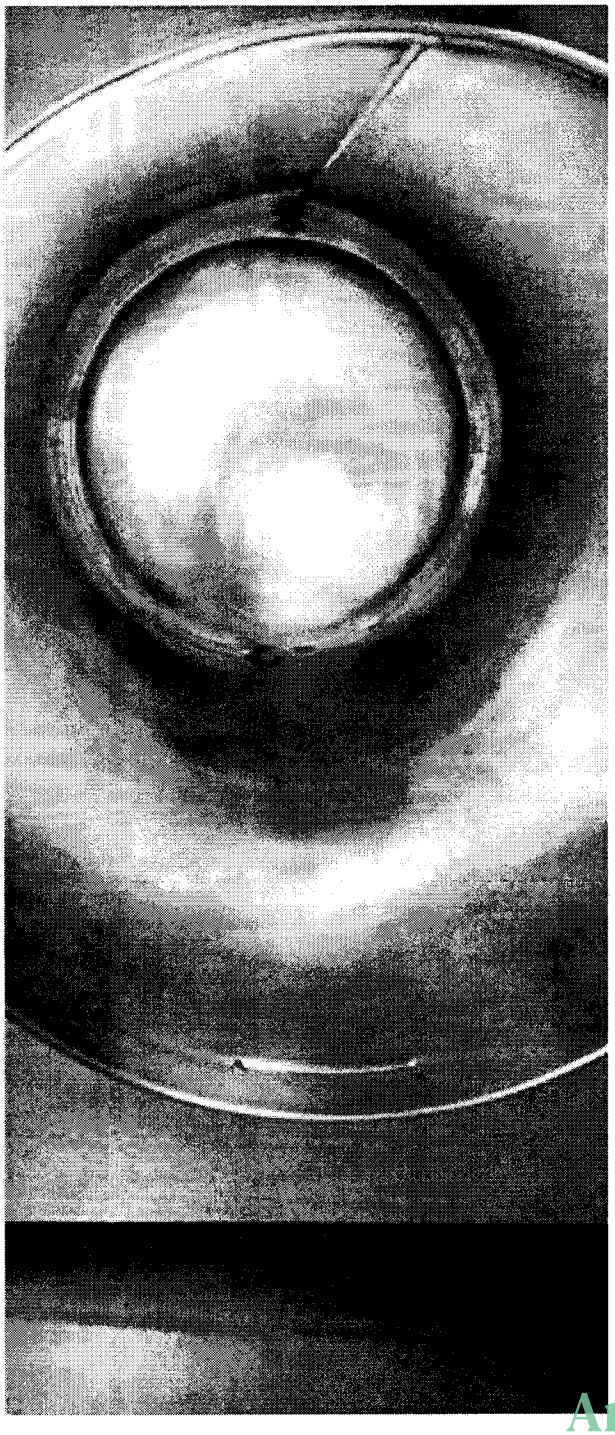
Outline of Attachments:

L1128-Item #1: F3- Pictures of Cleaned Autoclave machines as of 4/14/16.





L1128-Item #1: F3: Training Material provided to staff regarding cleaning and staff sign-in sheets.

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Administrative Chapter 7: Pharmaceuticals
PPFA Revised June 2014/ PPSLR-SWMO Imp. 3.31.15,revised 4.23.15

PHARMACEUTICAL SERVICES

7.1.1 Policies and Procedures – **must** include

Formulary of all drugs stocked in the affiliate that is reviewed annually

A. Consider the potential for medication errors when developing formulary. Look-alike, sound-alike drugs should be identified as being at "high risk" for potential error. Extra steps should be taken to ensure safety.

FYI - Look-alike, Sound-alike (LASA) Medications

List of additional therapeutic/pharmacologic classifications of drugs that may be ordered for clients to obtain at outside pharmacies

Provision of pharmaceuticals in accordance with all state/local laws and regulations

A drug control system that covers the interval from the time pharmaceuticals are ordered until they are provided to the client

Inspection of all drug storage areas to remove expired drugs

Designation of which staff may have access to bulk storage areas

Management of pharmaceutical product irregularities and drug and device recalls

7.1.2 Procurement

I. There **must** be a written order for all drugs/pharmaceuticals/chemicals brought into the affiliate:
   A. A copy of the purchase order or the prescription **must** be kept in the affiliate's files. A signed receipt **must** be obtained for pharmaceuticals shipped from a central location to outlying centers or clinics. If delivery is made by affiliate staff, a signed receipt is not necessary.
   B. Controlled substance order and receipt records **must** be filed separately from the other pharmaceutical purchase records.

II. If pharmaceuticals are routinely purchased from a community or hospital pharmacy and if the items are not supplied in manufacturer original containers, there should be a written contract specifying, at a minimum, requirements for labeling.

III. If available, pharmaceuticals should be purchased in manufacturer prepared unit-of-use packages.

IV. Only drugs and devices approved by the Federal Food and Drug Administration (FDA), and manufactured for sale in the United States may be used. Affiliates may not import drugs and/or medical devices from other countries for use in their health centers.

7.1.3 Storage

I. Access
   A. The bulk storage area **must** be secure.
   B. Controlled substances **must** be locked and in a secure area at all times.
   C. Access to pharmaceuticals dispensed from within client care areas should be limited to health care providers responsible for dispensing these items.

How to store

   D. Arrange medications so that the oldest stock is used first.
   E. Do not store look-alike, sound-alike medications alphabetically. Store them out of order or in a separate location.[RI]
   F. Pharmaceuticals meant for internal use **must** be stored separately (i.e., on a separate shelf) from those for external (i.e., topical) use only.

G. All prescription medications should be stored in containers that protect them from light.
H. All manufacturer recommendations for storage **must** be followed.

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Attached as PDF Documents:

L1128 Item #3: F1: PPFA-ARM's Infection Prevention Manual "Spore Testing Biological Indicator" Policy.

F2: Vendor Recommendations and Staff Sign-in Sheet

L1128 Item #5 F2: Staff Retraining Materials (Use of Self-adhesive sterilization pouch ; PPFA-ARMS Packing Instructions) and sign-in sheet for Staff Retraining on packaging of sterilized instruments

L1128-Item #1: F3: Training Material provided to staff regarding cleaning and staff sign-in sheets

L1153 Items #1 - #3 : F1: RHS of PPSLR Preprinted Physician's Order Sheet

L1153 Items #1 - #3 : F1: RHS of PPSLR Medication Administration Record (MAR)

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Storage for contraceptive vaginal ring (CVR)

I. An expiration date **must** be on the label of each ring package. If needed, use the adhesive labels provided in the carton.
J. For rings that will not be refrigerated, the adhesive label **must** be applied directly over the pre-existing expiration date on each cachet pouch (and on the outer carton). This date should not exceed either 4 months from the date of dispensing, or the product expiration date, whichever comes first.
K. For refrigerated NuvaRing, the product expiration date may be used.
L. NuvaRing packages that need to be refrigerated **must** be clearly marked.
M. NuvaRing should never be stored in direct sunlight or at temperatures above 30°C (86°F).

Store Mifepristone and misoprostol at room temperature.

Storage of multi-dose vials

N. Unopened multi-dose vials – **must** follow manufacturers' recommendation for storage
O. Opened multi-dose vials
    1. When a multi-dose vial is used, appropriate infection prevention procedures to prevent contamination should be employed.[R2]
    2. Vials **must** be discarded if there is evidence of contamination.
    3. If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial **must** be dated and discarded in accordance with manufacturer's instructions and state/local regulations.
    4. If no specific guidelines are provided, CDC recommends discarding the vial within 28 days. [R2]
    5. Syringes taken from multi-dose vials must be labeled with medication name, date, time and staff initials. If not used within 24 hours, it must be discarded.
    6. Open vials of misoprostol should be discarded after 30 days.
    7. Multi-dose vials (once opened) shall be kept in centralized location, (RHS-the nursing station in Recovery, HC- laboratory area).
P. Single use medications are used for one client only and are discarded after use on each patient.

Prescription pads

Q. Must be secured in medication cabinet when not in use.

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Packaging Instruments

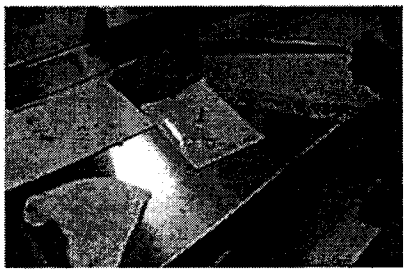
1

Place the instrument into the peel pack and add the indicator strip.

2

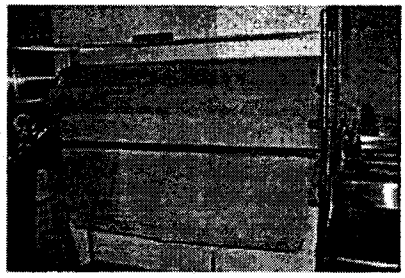
Fold over the edge of the peel pack and tape the edge of the peel pack closed using the sterilizer tape.

3



Write the date the instrument is packaged onto the sterilizer tape.

4



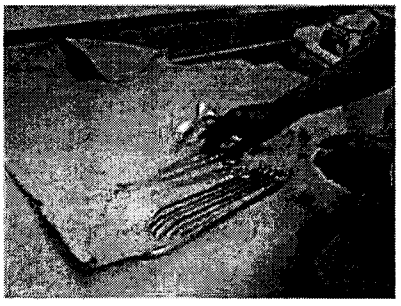
Traditional blue muslin wrapping paper for sterilization.

5

Place the sterilizing paper diagonally, or in a diamond shape, on the table.

Place the tray of instruments in the center of the paper so that the tray is horizontal (the widest part of the tray faces right and left).

6



Instruments to be packaged onto surgical trays for sterilization should be arranged in the tray so that there is space between the instruments to allow contact with the sterilizing agent.

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Washington, Carol

From: affil-psds@ppfa.org on behalf of Intondi, Evelyn <Evelyn.Intondi@armsinc.org>
Sent: Tuesday, April 19, 2016 2:27 PM
To: Affil Quality-Risk Management; Affil-PSDs
Subject: Clarification - Biological-Spore testing section of Infection Prevention Manual

Dear Colleagues,
I have received feedback and questions from many of you regarding the section of the Infection Prevention Manual on Biological/Spore Autoclave testing. I appreciate your responses and have made a few revisions to pages 23 and 24 for further clarification.

p.23
Each autoclave must have a minimum of weekly spore testing. Best practice suggests spore testing every day that surgical and other instruments are sterilized. Affiliates must follow state/local requirements and may choose to adopt more conservative testing on a daily basis.

p.24
If there is a single positive biological indicator result, the load(s) do not need to be recalled unless the sterilizer is defective as determined by maintenance personnel or incorrect cycle settings. If additional tests remain positive, consider the items nonsterile and recall and reprocess items from the load. The cause of the positive result should be investigated.

The updates have been made in the Infection Prevention Manual posted on ARMS Connect
Thanks very much.

Best regards,
Evelyn

arms

Evelyn Intondi CNM | Director of Risk, Quality, and Patient Safety
Affiliates Risk Management Services, Inc.
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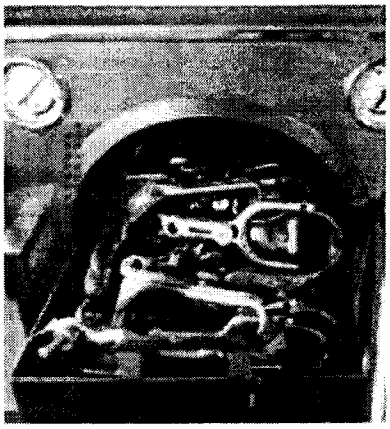

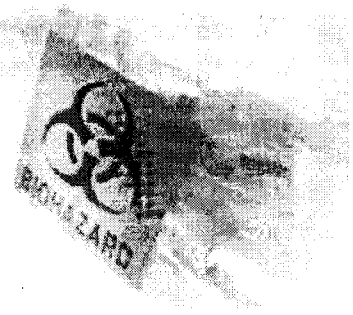

Infection Prevention **Manual**

Americans United for Life

arms

We would like to thank the following contributors to the revision of this manual:

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AED Review

Biological/Spore Autoclave Testing

Each autoclave must have a minimum of weekly spore testing. Best practice suggests spore testing every day that surgical and other instruments are sterilized. Affiliates must follow state/local requirements and may choose to adopt more conservative testing on a daily basis.

It is also essential to conduct biological testing if:

- A new type of packaging material or tray is used
- After training new sterilization personnel
- After a sterilizer has been repaired
- After any change in sterilizer loading procedures

CDC resource for sterilization monitoring:

http://www.cdc.gov/OralHealth/infectioncontrol/faq/sterilization_monitoring.htm

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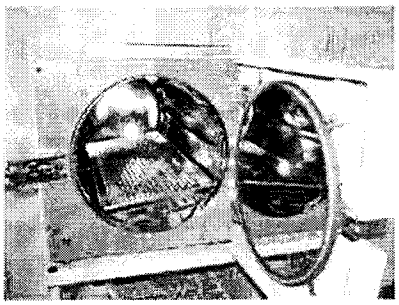
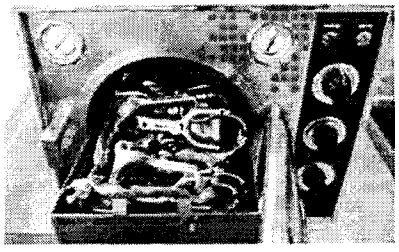
Removing Load from Sterilizer

- Load should be dry and cool when removed.
- Care must be taken to keep sterile items separated from non-sterile items.



Loading the Sterilizer: do not overfill

Speculums may be sterilized without wrapping



Example of sterilizer that is too full

How Steam Sterilization Works

Saturated steam under pressure by autoclave is a way of producing moist heat, and is the most dependable for sterilization. Sterilization begins when water is heated to 212°F (100°C). The steam that forms is submitted to increasing pressures within the sterilizer, which causes an increase on the temperature of the steam. The higher the pressure in the sterilizer, the higher the temperature of the steam. As steam enters the sterilizing chamber, the relatively cool air already present, being much heavier than the steam, will be driven to the bottom of the chamber. The saturated steam permeates the material within the chamber and gives up heat in the process. The transfer of the heat from steam to the material results in condensation of the steam vapor back into water droplets, which moisten the sterilized material. Only those articles that are permeated and moistened by the steam will be adequately sterilized. Cool air is constantly eliminated from the chamber to permit adequately high temperature and permeation of the package wrapping by the steam.

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If performing biological testing at the affiliate:

- The placement of a biological indicator in the load is critical. It should be located in the most challenging location of the sterilizer and according to the manufacturer's recommendations. The biological indicator should be placed in a tray and not laid directly in the surface of the sterilizer.

Instruments	PCD (BI Challenge Pack Test)
Unwrapped Instruments	Place a BI and CI (chemical indicator) on a tray with instruments normally sterilized. Process in a full load in front of the bottom tray
Wrapped	Place BI and CI in a wrap with items normally sterilized. Process in a full load in the front of the bottom tray
Pouches	Place the BI and CI in a peel pouch with instruments normally sterilized. Process in a full load in the front of the bottom tray.

- If there is a single positive biological indicator result, the load(s) do not need to be recalled unless the sterilizer is defective as determined by maintenance personnel or incorrect cycle settings. If additional tests remain positive, consider the items nonsterile and recall and reprocess items from the load. The cause of the positive result should be investigated.
- The results of the biological test must be documented in a log book or file and maintained for three years (check state/local requirement). The documentation must include the date the test was carried out and the name of staff member(s) who performed the test and read the results.
- If sending biological autoclave test to lab, results must be filed and kept for three years.

Management of Positive Biological/Spore Test Indicators in a Steam Sterilizer

The following is the recommended procedure to follow when spore tests are positive indicating growth.

Clinical staff should be familiar with the following procedure:

1. Immediately check the autoclave for proper use and function and repeat the spore test. A single positive spore test result probably does not indicate sterilizer malfunction. Objects do not need to be re-sterilized because of a single positive spore test unless the sterilizer or the sterilization process is found defective. Sterilizer should be removed from service and sterilization operating procedures reviewed to determine whether operator error could be responsible.
2. All sterilization indicator strips must continue to turn the appropriate color.
3. If a spore test remains positive:
   - discontinue use of the autoclave
   - immediately notify supervisor
   - remove all sterilized packs from inventory dated after the last negative spore test result
   - use alternative equipment (e.g. disposable speculum)
   - call for service

When repair is completed, rerun biological spore test prior to sterilizing equipment for use.

Documentation

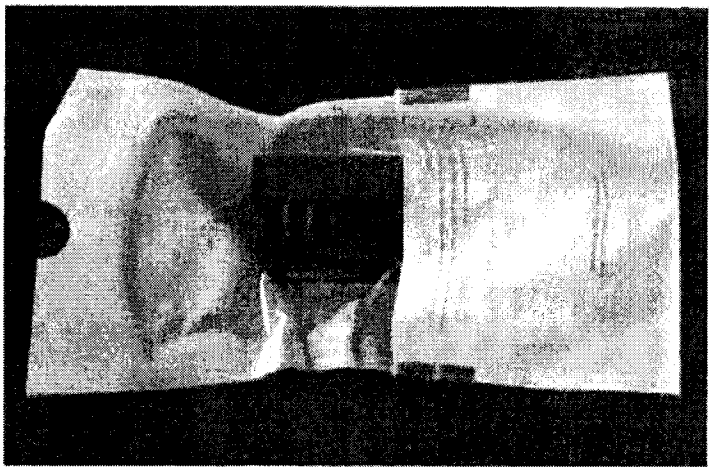
Documentation establishes accountability by documenting what instruments have been processed and provides monitoring controls evidence for those items. In the event of a sterilization process failure, good records will help the staff trace each package back to the event itself. Each item or pack should be labeled with a lot identifier that designates the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). Lot identification enables retrieval of items in the event of a recall, tracing problems to their source and facilitate proper stock rotation.

RDH

Using a self-adhesive sterilization pouch

by Noel Kelsch, RDHAP
n.kelsch@sbcglobal.net

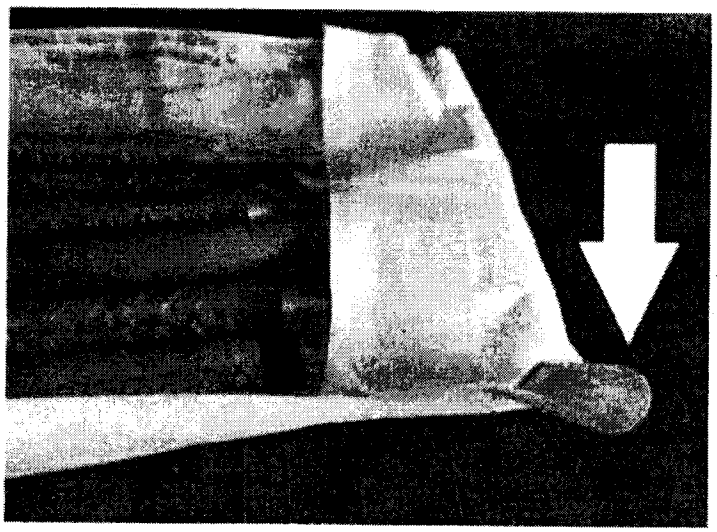
I went to an office today and witnessed someone tripping really hard. It was not her feet that she was tripping over; it was infection control.



Do not fold over to fit item, or fold on crease or perforation.

Infection control is a series of steps that we must perform to ensure the safety of our staff and clients. When we do not follow those steps precisely, we might as well not follow those steps at all. The step being tripped on was a simple self-adhesive sterilization bag. Sterilization pouches are approved by the Food and Drug

Administration and are a medical device. The 2008 Center for Disease Control and Prevention guidelines reminded us that these devices "must allow penetration of the sterilant, provide protection against contact contamination during handling, provide an effective barrier to microbial penetration, and maintain the sterility of the processed item after sterilization."



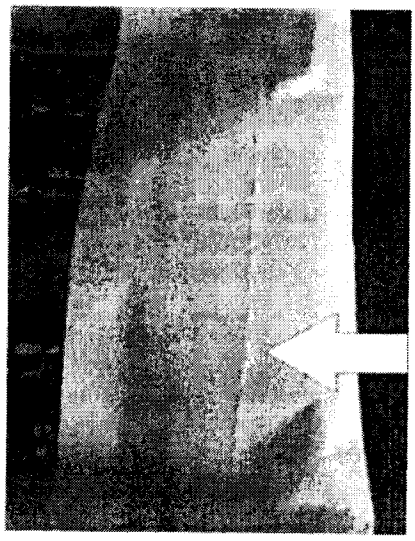
Improper gap.

The method of using them involves a series of steps, starting with the sterilization room:

- **Step one:** Fold the perforation back and crease with the protective strip still in place. Fold back into place.
- **Step two:** Write the date and time, or load number, on the outside of the pouch, with a lead–free pencil or nontoxic indelible ink pen.1 This will allow you to pull the load easily if you receive a failed load report. Record the load type, date, and number in your sterilization notebook.2
- **Step three:** While wearing utility gloves and personal protective equipment, load the dried, debris-free instruments (that have been run through the sonic cleaner) into the pouch. Be sure not to overfill the bag. It should be filled only to 3/4 of its volume. Make sure the instruments do not pierce the package. Choose the right size bag for the item. Do not over fill or fold for smaller items. The pouch is correctly sealed when the closure strip adheres without any folds or gaps.

- **Step four:** Expel excess air from the package.
- **Step five:** Remove the strip from the adhesive, fold at perforated line to form a tight seal. Press the adhesive together by running the edge of spatula or flat item across the area. Allow the adhesive to adhere to 50% to be on paper and 50% to be on plastic, or follow the validation marks on the pouch. Do not fold the adhesive past the perforation. Adhesive not touching the right amount of paper and plastic will not create an airtight seal.

The adhesive strip is a vital part of the process. It creates a seal after the material has expanded and



The fold line is in the wrong place. Always fold on the perforation.
contracted. A properly designed pouch allows for the 50% coverage of paper and 50% coverage of plastic with the adhesive.

An adequate width of adhesive material with a clean perforated fold allows for a clean, uniform fold and seal, which assures safe storage of the sterilized item and does not allow air and pathogens to enter the item.

Companies now make validation marks on the package to ensure you are closing it properly. Make sure you have the perforation line folded and lined up before removing the adhesive strip.

- **Step six:** Store filled packages on the dirty side of the sterilization area until ready to process.

Chairside:

Do not put your gloves on until you have opened the pouch. Contaminates from the outside of the package can contaminate your gloves. When you touch the instruments with the gloves, you can cross-contaminate.

Do not put the outside of the package on top of the instruments or on the tray. The outside of the package has been exposed to contaminate and is not sterile.

As you open the pouch, allow the instruments to "drop" onto the tray so that they are not contaminated by the outside of the package.

Each of us has a responsibility to keep our patients and staff safe. Using the FDA-approved device properly step by step allows all of us to avoid "tripping" and putting everyone at risk.

References

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. 2006. Arlington, VA: AAMI.
2. Palenik CJ, Burke FJT, Coulter WA, Cheung SW. Cross-Infection Control, Improving and Monitoring Autoclave Performance in Dental Practice. Brit Dent J. 1990;187:581–84

Noel Brandon Kelsch, RDHAP, is a syndicated columnist, writer, speaker, and cartoonist. She serves on the editorial review committee for the Organization for Safety, Asepsis and Prevention newsletter and has received many national awards. Kelsch owns her dental hygiene practice that focuses on access to care for all and helps facilitate the Simi Valley Free Dental Clinic. She has devoted much of her 35 years in dentistry to educating people about the devastating effects of methamphetamines and drug use. She is a past president of the California Dental Hygienists' Association.

Tips to remember:

- Store unused pouches in a cool, dry place before use. Heat and moisture can compromise the indicator, adhesion, and materials.
- To check if your pouch is able to achieve a proper seal and that you are doing the process correctly, simply do a water test. Seal the pouch with nothing inside. Open the opposite end of the seal and add water halfway up. If it is leaking, it has not been sealed properly or the seal material is inadequate.
- Many companies have instructions and videos to help you learn how to use their pouches.
- It is important that pouches do not come into contact with the chamber wall. Do not overload the chamber. The most effective way to load the sterilizer is to follow the manufacturer's diagram for loading. Most units are loaded vertically, allowing the most access to the sterilant. If the unit requires you to load horizontally, make sure the pouches do not touch one another so that there is a maximum amount of exposure.
- Training must occur for every staff member using this device. Any staff that is involved in sterilization must be trained and retrained if a new product is put into use or the old product has a new feature.
- Do not remove sterilization pouches from the sterilization device until it has been fully processed and is dry. Wet items can wick pathogens back into the package.
- Shelf life for sterilized pouches is now considered event related. If the sterilization pouch is stored in a drawer that is allowing the pouch to move around and pierce the side, it will have to be reprocessed using a fresh bag. Life of the bag depends on the handling, movement, and environment. Check each bag for compromise before use.
- The plastic must be completely separate from the paper when tearing the pouch open. The outside of the plastic has been exposed to the environment and pathogens may be present on the outside of the package. If the plastic is adhered to the paper, there is a chance of cross-contamination if the instruments touch the plastic. Test your pouches before using by simply tearing the plastic from the paper. If the plastic adheres, return the supply to the manufacturer.

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Reproductive Health Services of Planned Parenthood of the St. Louis Region

PRE-PRINTED PHYSICIAN'S ORDER SHEET

The medications **checked below ☑ are ordered by me**, the treating physician, for care to be provided for this patient in accordance with RHS of PPSLR Medical Standards & Guidelines.

ATTENDING: □ **Dr. Crist** □ **Dr. Eisenberg** □ **Dr. Madden** □ **Dr. McNicholas** □ **Dr. Kreusser** □ **Dr. Hiliker** □ **Dr. Gray-Swain**

ATTENDING MD Signature_____ Date_____ Time_____□ am □ pm

Fellow MD/WHNP Signature_____ Date_____ Time_____□ am □ pm

Patient's **ALLERGIES:** _____ PROCEDURE: _____

☑	MEDICATIONS			☑	MEDICATION Dispensed with discharge		
	Azithromycin 250 mg tab PO		Misoprostol 200mcg buccal		Acetaminophen 325 mg #20 Sig: □ **1 tab PO q 4**		Doxycycline 100 mg #14 Sig: 1 PO BID x 7 days
	Azithromycin 500 mg tab PO		Misoprostol 200mcg buccal **(Repeat x1)**		Acetaminophen 325 mg #20 Sig: **2 tabs PO q 6 hours**		Ibuprofen 600mg #10 Sig: 1 PO q 6 hrs.
	Acetaminophen 500 mg tab PO		Ondansetron 4 mg ODT SL		Acetaminophen 500 mg #30 Sig: **1 tab PO q 4**		Metronidazole 500mg #14 Sig: 1 PO BID x 7 days
	Ceftriaxone 250 mg IM		Ondansetron 4mg/2ml □ **IM or** □ **IV**		Acetaminophen 500 mg #30 Sig: **2 tabs PO q 8 hours**		Misoprostol 200mcg # 4 Sig: 4 tabs buccal
	Diphenhydramine 25 mg PO		Promethazine 25 mg PO		Azithromycin 250 mg #4 Sig: **4 tabs PO x 1 dose**		Methergine 0.2 mg tab #6 Sig: 1 PO q 8 hrs.
	Diphenhydramine 50 mg/mL IVP		Rh(o) Immune Globulin 50 mcg (Mini) IM	☑	EXTERNAL RX		
	DMPA 150 mg IM		Rh(o) Immune Globulin 300 mcg (Full) IM		Acetaminophen 325mg/Codeine 30mg # 6 Sig: 1 PO q 4-6 hr PRN pain		
	Doxycycline 100 mg Tabs PO		IV Saline Lock		Hydrocodone 5mg/ Acetaminophen 325mg #10 Sig: 1 PO q 4-6 hours PRN pain		
	Fentanyl 50mcg/1 mL		Lactated Ringers 500 mL IV		Promethazine 25 mg PO # 6 Sig: 1 PO q 6-8 hrs PRN Nausea		
	Fentanyl 50mcg/1 mL **(Repeat x1)**		Lactated Ringers 500 mL IV		Name of OCP :_____# 13 cycles, Sig: 1 PO daily		
	Ibuprofen 600mg 1 tab PO		Lactated Ringers 1000 mL IV				
	Ibuprofen 80mg 1 tab PO		Lactated Ringers 1000 mL IV				
	Ketorolac 30 mg □ **IM or** □ **IV**						
	Methergine 0.2 mg IM						
	Metronidazole 500 mg PO						
☑	MEDICATION ABORTION						
	Mifepristone 200 mcg						
☑	MEDICATION for MODERATE SEDATION (IV)						
	Diazepam 5 mg tab PO						
	Fentanyl 50mcg/1 mL						
	Midazolam 2mg/2mL						
☑	EMERGENCY MEDICATION						
	Atropine 1mg/mL		**Naloxone 0.4 mg/mL**				
	Diazepam 5m/mL IVP		**Vasopressin 20units/mL/10ml vial**				
	Flumazenil 1 mg/10mL						

Medication Lot numbers entered in NextGen by:_____Date:_____

This PHYSICIAN ORDER SHEET was scanned into NextGen by:_____Date:_____

Name_____

DOB_____ MRN_____

CAN ALSO PLACE PATIENT LABEL INSIDE THIS BOX

Americans United for Life

Sterilizer Monitoring & Compliance

Use of a Control

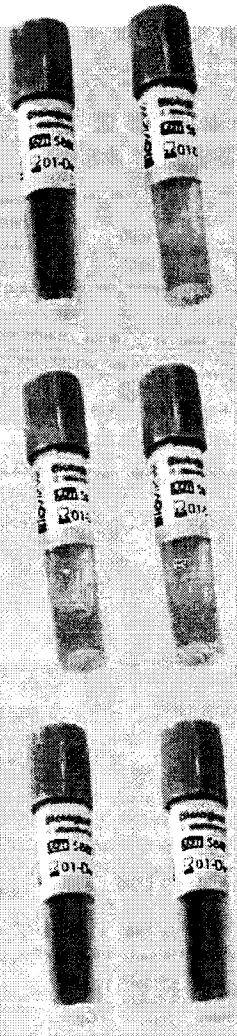
Incubate a non-processed, activated Bioview indicator at the same time as your test. A control:

- ensures spore viability
- demonstrates the capability of the growth media to promote growth
- confirms that the incubator is functioning properly

CDC: Centers for Disease Control and Prevention

"A control biological indicator, from the same lot as the test indicator and not processed through the sterilizer, should be incubated with the test biological indicator: the control biological indicator should yield positive results for bacterial growth".

Results	Interpretations
Pass Negative Test (**purple**) Positive Control (**yellow**)	Spores were killed. The Sterilization process was successful.
Fail Positive Test (**yellow**) Positive Control (**yellow**)	Sterilization process failure. Determine cause for sterilization process failure. Repeat the spore test.
Invalid Negative Test (**purple**) Negative Control (**purple**)	There is a problem with spore vitality, the growth media or the incubator. Check expiration dating of Bioview indicators used. Repeat test. If results are the same, incubator may not be functioning properly.



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sporetesting@mesalabs.com

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8.3 *Cleaning the Air Jet*

(Located in the water reservoir.)

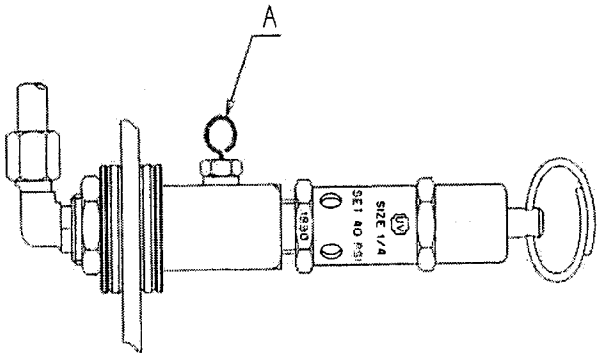
A dirty air jet is the number one cause of failed spore tests

The elimination of air from the sterilization chamber during heat up is **critical** to the proper operation of the autoclave. Failure of the air removal system will be responsible for incomplete sterilization, indicator strips that do not change color and failed spore tests.

The air jet consists of a small orifice with a clean out wire inserted in it (wire is permanently installed and will not come out). It is required that the air jet be cleaned once per week or more often if necessary, to remove any accumulated dirt and debris.

It is preferred to clean the air jet when the unit is running a cycle and under pressure. This is so that any loosened debris will be blown away, however, it can be done while the unit is idle.

1. Remove the water reservoir cover.
2. Clean the hole of the jet by manipulating the air trap wire (A) back and forth 10 times. [~ 1/2" TOTAL MOVEMENT]



Note:
It is important to clean the hole of the air trap, as described in point 2 before starting operation of the autoclave, for the first time.

PER BOB @ TUTTNAUER - USE A PENCIL TO MANIPULATE THE AIR TRAP WIRE

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Infection Control Report - Sterilization Monitoring

Prepared for: Planned Parenthood - RHS of PPLSR

Monday, April 18, 2016

Requirements and recommendations of Missouri

It is required to spore test weekly in Missouri.

Agency: Missouri Dental Board

Source: Infection control procedures--requirements and training for health care facilities and professionals. (191.694.1)

Relevant text: 1. All health care professionals and health care facilities shall adhere to universal precautions, as defined by the Centers for Disease Control of the United States Public Health Service, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments, to minimize the risk of transmission of HIV, HBV and other blood-borne infections to patients. Health care professionals and health care facilities shall comply with current guidelines, established by the Centers for Disease Control, for disinfection and sterilization of reusable devices used in invasive procedures.

For further information: http://www.moga.mo.gov/mostatutes/stathtml/19100006941.HTML
573-751-0040

Recommendations of national organizations

It is recommended to spore test weekly by the CDC.

Agency: Centers for Disease Control and Prevention

Source: Guidelines for Infection Control in Dental Health-Care Settings --- 2003

Relevant text: VI: Sterilization and Disinfection of Patient-Care Items

E. Sterilization of Unwrapped Instruments
2. Use mechanical and chemical indicators for each unwrapped sterilization cycle (i.e., place an internal chemical indicator among the instruments to be sterilized) (IB).

F. Sterilization Monitoring
1. Use mechanical, chemical, and biological monitors according to the manufacturer's instructions to ensure the effectiveness of the sterilization process (IB).
2. Monitor each load with mechanical (e.g., time, temperature, and pressure) and chemical indicators (II).
3. Place a chemical indicator on the inside of each package. If the internal indicator is not visible from the outside, also place an exterior chemical indicator on the package (II).
4. Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant (IB).
5. Do not use instrument packs if mechanical or chemical indicators indicate

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inadequate processing (IB).
6. Monitor sterilizers at least weekly by using a biological indicator with a matching control (i.e., biological indicator and control from same lot number) (IB).
7. Use a biological indicator for every sterilizer load that contains an implantable device. Verify results before using the implantable device, whenever possible (IB).
8. The following are recommended in the case of a positive spore test:
a. Remove the sterilizer from service and review sterilization procedures (e.g., work practices and use of mechanical and chemical indicators) to determine whether operator error could be responsible (II).
b. Retest the sterilizer by using biological, mechanical, and chemical indicators after correcting any identified procedural problems (II).
c. If the repeat spore test is negative, and mechanical and chemical indicators are within normal limits, put the sterilizer back in service (II).
9. The following are recommended if the repeat spore test is positive:
a. Do not use the sterilizer until it has been inspected or repaired or the exact reason for the positive test has been determined (II).
b. Recall, to the extent possible, and reprocess all items processed since the last negative spore test (II).
c. Before placing the sterilizer back in service, rechallenge the sterilizer with biological indicator tests in three consecutive empty chamber sterilization cycles after the cause of the sterilizer failure has been determined and corrected (II).
10. Maintain sterilization records (i.e., mechanical, chemical, and biological) in compliance with state and local regulations (IB).

Recommendation categories
o Category IA: Strongly recommended for implementation and strongly supported
o Category IB: Strongly recommended for implementation and supported
o Category IC: Required for implementation
o Category II: Suggested for implementation

For further information: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a1.htm

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It is recommended to spore test weekly by the ADA.

Agency: American Dental Association

Source: Monitoring Sterilizers

Relevant text: Biological Indicators:
Monitor sterilizers at least weekly with biological (spore) indicators. Check whether your state dental board has different requirements.
Consider using biological (spore) indicators daily if the sterilizer is used frequently (e.g., several loads per day). Daily monitoring allows for earlier discovery of equipment malfunctions or procedural errors.
A positive spore test result indicates that sterilization was incomplete.
Maintain a log of spore test results. Check your state regulations to determine how long you need to keep spore testing records.

For further information: http://www.ada.org/4079.aspx

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It is recommended to spore test weekly by the AAMI.

Agency: Association for the Advancement of Medical Instrumentation

Source: AAMI: Steam Sterilization and Sterility Assurance, 7.5.4 Test Frequency

Relevant text: "Biological indicators must be used no less than weekly for each sterilizer and, preferably, should be used for each load. More frequent testing should be carried out on an as needed basis (I.E., after major sterilizer repairs, when evaluating sterilization of new products, when implantable or intravascular materials are sterilized, etc.)"

It is recommended to spore test weekly by the AORN.

Agency: Association of Perioperative Registered Nurses

Source: Recommended Practices, Sterilization & Disinfection, 1987.

Relevant text: "For routine monitoring should be used weekly, and as needed; each load of implantables."

It is recommended to spore test weekly by the VA.

Agency: Veteran's Administration

Source: VA Manual G1, MP-2, 1985 and MP-2, Sub-chapter E, Change 159, June 22, 1983.

Relevant text: "Must be sterilized no less than weekly, each load of implantables or intravascular materials, following major sterilizer repairs, new products or packaging material."

If you have questions or need more information, please call North Bay at (800) 289-7786

Disclaimer: Regulations provided for educational purposes. Each office must determine their testing frequency. Contact your State Dental Board for current regulations.

Americans United for Life

Missouri Revised Statutes

Chapter 191
Health and Welfare

←191.692

Section 191.694.1

191.695→

August 28, 2015

Infection control procedures--requirements and training for health care facilities and professionals.

191.694. 1. All health care professionals and health care facilities shall adhere to universal precautions, as defined by the Centers for Disease Control of the United States Public Health Service, including the appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments, to minimize the risk of transmission of HIV, HBV and other blood-borne infections to patients. Health care professionals and health care facilities shall comply with current guidelines, established by the Centers for Disease Control, for disinfection and sterilization of reusable devices used in invasive procedures.

2. Health care professionals who have exudative lesions or weeping dermatitis of the hands, forearms, or other locations that may contact patients, particularly on exposed areas such as hands or forearms, shall refrain from performing all invasive procedures, and from handling patient-care equipment and devices used in performing invasive procedures until the condition resolves.

3. As a condition for renewal of a certificate of registration or authority, permit, or license, all health care facilities shall provide satisfactory evidence that periodic training in infection control procedures, including universal precautions, is provided to all personnel who perform patient care services at or from such facilities. Regulations for such training shall be promulgated by the state regulatory authorities or bodies responsible for licensing the respective health care facilities.

4. All health care professionals who perform invasive procedures shall receive training on infection control procedures relevant to HIV and related diseases, including universal precautions and prevention of percutaneous injuries, appropriate for their specialty and approved by the department of health and senior services. The department of health and senior services, in cooperation with appropriate state regulatory authorities responsible for licensing the respective health care professionals and in cooperation with professional societies, shall develop regulations for such training. The requirements set forth in this subsection shall be deemed satisfied if the health care professional completes the training provided in accordance with the provisions of subsection 3 of this section.

(L. 1992 S.B. 511 & 556 § 191.694 subsecs. 1 to 4)

Top

Missouri General Assembly

Americans United for Life

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Care. No matter what.

RHS of PPSLR Medication Administration Record (MAR)

Name: ______________________ D.O.B.________ MRN:____________ Date: ____________

Procedure: ☐ Surgical Ab ☐ Medical Ab **Allergies(Ask patient & Record):**

☐ Miscarriage Mgt. ☐ (other)______________

Medication Drug Name, Dosage, Route	**Time**	**initials**	**initials**	**initials**	**initials**	**Medication** Drug Name, Dosage, Route	**Time**	**initials**	**initials**	**initials**	**initials**	**Medication** Drug Name, Dosage, Route	**Time**	**initials**	**initials**	**initials**	**initials**
Prescribed By: ☐ Crist ☐ Eisenberg☐ Madden ☐ McNicholas ☐ Kreusser ☐ Hiliker						**Prescribed By**: ☐ Crist ☐ Eisenberg☐ Madden ☐ McNicholas ☐ Kreusser ☐ Hiliker ☐ Gray-Swain						**Prescribed By**: ☐ Crist ☐ Eisenberg☐ Madden ☐ McNicholas ☐ Kreusser ☐ Hiliker ☐ Gray-Swain					
Prescribed By: ☐ Crist ☐ Eisenberg☐ Madden ☐ McNicholas ☐ Kreusser ☐ Hiliker						**Prescribed By**: ☐ Crist ☐ Eisenberg☐ Madden ☐ McNicholas ☐ Kreusser ☐ Hiliker ☐ Gray-Swain						**Prescribed By**: ☐ Crist ☐ Eisenberg☐ Madden ☐ McNicholas ☐ Kreusser ☐ Hiliker ☐ Gray-Swain					
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NOTE: Any refusal or failure to administer at the prescribed time should be noted with an "E". Explain reason/circumstances/follow-up for all "E" notations here:

KEY:

Staff Name Administering Medication	**Title**	**Initials**

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1128 (Findings #1-3)	1. <u>Sterilizers should be inspected and cleaned daily according to manufacturer's written instructions.</u> RHS OF PPSLR will contact manufacture of autoclave (sterilizer) to determine appropriate product to address the discoloration. Manufacture will perform the appropriate professional cleaning. RHS OF PPSLR currently uses chamber brite and will continue to evaluate current staff utilization of this product to disinfect the autoclave.	4/15/16 4/15/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education.	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	F3: Picture of the cleaned autoclave machines as of 4/14/16. F3: Training Material provided to staff and staff sign-in sheet.
L1128 (Findings #4-7)	2. <u>Sterilizers maintenance should be documented timely and appropriately</u> Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include mention of performing a biological indicator with every load and containing a supervisory review. Conduct staff review of training updated Sterilization Room Humidity, Temperature and Autoclave maintenance Log and on appropriate and timely documentation of sterilizer maintenance and inclusion of "out of service" notation when equipment is not in service.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Staff training will be conducted on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log.	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
				Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #8-12)	3. <u>Ensure biological indicators are utilized according to manufacturer's written instructions and documentation is appropriate.</u> RHS of PPSLR will utilize a new biological indicator product (Sterile Check). As per ANSI/AAMI ST79, RHS of PPSLR shall follow the manufacture's written instructions (e.g., 2 BI with every load). Update existing Sterilization Room Humidity, Temperature and Autoclave maintenance Log to include that every load shall contain 2 biological indicators and incorporate the additional signature to capture the supervisory review. Staff Training will be conducted on updated product, process and documentation requirements. Revise existing Clinical Area Procedure Manual to reflect (a) the manufacture's recommendation (e.g., 2 BI with every load) , (b) documentation requirements, and (c) associated forms for resulting BI results. Revise existing PPFA - ARMS policy titled: Spore Testing Biological Indicator to reflect the manufacture's recommendation of 2 BI with every load.	5/20/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality, Training & Education	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring -Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	F1: PPFA-ARM's Infection Prevention Manual "Spore Testing Biological Indicator" Policy. F1: Sterile Check (Biological Indicator Product) Manufacture's Instruction
L1128 (Findings #13-15)	4. <u>Ensure procedure is in place to prevent cross-contamination and separation of dirty instruments</u> RHS of updated current process to ensure that functional areas are physically separated (e.g. closure of pass through window) during phases of reprocessing.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training	Supervisory observation and monitoring compliance has been modified to increase frequency and level of scrutiny to daily through use of modified weekly audit tool to a daily audit tool. -Lead MA will ensure daily monitoring	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	RHS of PPSLR shall revise existing monthly site review to include specific criteria for decontamination & sterilization areas/process. Staff in-service on these revised processes to ensure full dissemination of information.		and Director of Quality, Training & Education	-Quality /Training Coordinator will ensure weekly review /audits -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor compliance of plan. Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on revised Sterilization Room Humidity, Temperature and Autoclave maintenance Log. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #16-21)	5. <u>Follow manufacture's instruction for packaging of sterilized instruments</u> PPSLR-RHS will purchase individualize instrument sterile peel packs, provide training to staff on the proper use of the individualized peel packs as indicated by the manufacture it relates to closure of package . PPSLR-RHS will reprocess all instruments formerly processed as the staff retraining is performed.	4/30/16	Director of Surgical Services; and Coordinator of Quality/ Training	Director of Surgical Service and Coordinator of Quality/Training shall conduct staff training on the manufacturer's instructions for the sterilization peel packs. Staff sign-in attendance sheet will be submitted as evidence.	F1: PPFA-ARM's Infection Prevention Manual "Packaging Instructions" Policy. F2: Staff Re-training and sign-in sheet for packaging of sterilized instruments.
L1128 (Findings #26)	6. <u>Restriction of multi-dose vials to centralized medication area from procedure room.</u> Revise existing PPSLR Policy titled Pharmaceutical	4/30/16	Director of Surgical Services; Coordinator	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Practitioner.	F1: Pharmaceutical Services Policy.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for multi-dose vial usage. -Staff training for Pharmaceutical Services Policy to include: 1. Revised procedure for restricted medication area for multi-dose medications 2. Procedural review of usage, storage & discarding of multi-dose medications and controlled substance inventory management		of Quality/ Training and RHS Nurse Practitioner	Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #27-29)	7. <u>Restriction of single -dose vials to single patient use medication area</u> <u>from procedure room</u> Revise existing PPSLR Policy titled Pharmaceutical Services to include language of "discard if open and unused single dose vial". Retrain staff on the updated PPSLR Policy titled Pharmaceutical Services and the workflow of the procedure preparation area for single-dose vial usage.	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and RHS Nurse Practitioner	Staff training on revised Pharmaceutical Services Policy will be conducted by Nursing and Training Coordinator and RHS Nurse Practitioner. Staff sign-in attendance sheet will be submitted as evidence.	F1: Pharmaceutical Services Policy.
L1128 (Findings #34-45)	8. <u>Ensure clean, free from dust surfaces of equipment, drawers, shelves and other horizontal surfaces</u> Increase service areas and frequency of environmental cleaning performed by the environmental service technician (EVS tech).	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and	Staff training on updated processes: environmental cleaning areas/frequency and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator. Staff sign-in attendance sheet will be	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	Provide training for EVS Tech on the updated span of areas to be cleaned and frequency. Update existing RHS audit checklist to include "removal of corrugated boxes in all patient care/storage areas".		Director of Quality Training, and Education	submitted as evidence.	
L1128 (Findings 46-49)	9. <u>Ensure expired supplies not available for patient use</u> RHS of PPSLR shall conduct staff in service on: 1. Expired inventory management, 2. Revisions to existing weekly audit tool to reflect a daily and location specific tool (e.g. ultrasound and lab will have a daily audit tool).	4/30/16	Director of Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	Staff training on updated processes: expectations and policy on expired inventory management and updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator. Staff sign-in attendance sheet will be submitted as evidence.	
L1128 (Findings #50-54)	10. <u>Ensure glucometer is approved by manufacturer for multi-clinical use</u> RHS of PPSLR will purchase new multi-use glucometers. Training of staff on the approved manufacture's instruction for daily cleaning and disinfection. RHS of PPSLR shall update current policy to include the manufacture's recommendations for cleaning and disinfecting the new multi-use glucometers.	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and RHS Nurse Practitioner	Staff training on updated processes: understanding and use of multi-use glucometer will be conducted by Nurse and Training Coordinator, RHS Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1128	11. <u>Ensure medication refrigerator temperatures are maintained</u>	4/30/16	Director of	Staff training on updated processes: ensuring	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
(Findings 55-59)	Modify existing policy titled: "Laboratory Refrigerator" to include range, action and re-check. Retrain staff on updated policy: Laboratory Refrigerator to include actionable steps when findings are out of appropriate range to be in accordance with manufacture's recommendations. Update the current RHS of PPSLR refrigerator Temperature Log.		Surgical Services; Coordinator of Quality/ Training and Director of Quality Training, and Education	proper and accurate documentation or medication refrigerator and review of updated audit tool will be conducted by Director of Quality, Training and Education and Quality/Training Coordinator and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1128	12. Ensure use of heating electrical devices is aligned with FDA/CPSC Public Health Advisory Guidelines RHS of PPSLR will institute the use of a new product: Disposable heating packs in lieu electrical heating pads. Training of staff on the manufacturer's instructions for use of the disposable heating packs.	4/30/16	Director of Surgical Services; Nursing and Training Coordinator and RHS Lead Nurse Practitioner	Staff training on updated processes: use of disposable heating packs will be conducted by Nurse and Training Coordinator, RHS Lead Nurse Practitioner and Director of Surgical Services. Staff sign-in attendance sheet will be submitted as evidence.	
L1137 (Findings #1,4-9)	1. Ensure criminal background checks are performed consistently. All RHS of PPSLR final candidates for employment and volunteer positions will have criminal background checks performed prior to employment offer. New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that criminal background checks have been performed.	4/30/16	Vice President of Human Resources and Compliance	VP of HR shall ensure that the completions of criminal background checks are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity. Existing volunteers currently staffed will receive a criminal background check by due date. New Hire Checklist audit will be conducted within the 1st week of every month by VP of HR and Compliance to ensure compliance .	
L1137	2. Ensure employee disqualification list inquiries are	4/30/16	Vice	VP of HR shall ensure that the completions of	

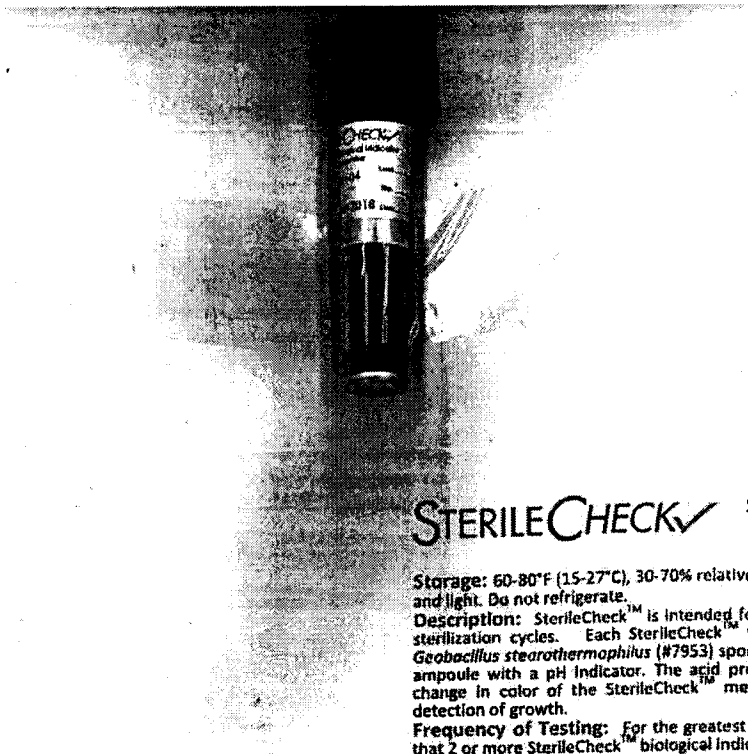
A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
(Findings #2,6-7,6)	consistently conducted. All RHS of PPSLR final candidates for employment and volunteer positions will have disqualification list inquiries checks performed prior to employment offer. New hire audit will be conducted on all RHS of PPSLR final candidates for employment and volunteer positions on first day to confirm that disqualification list inquiries checks have been performed.		President of Human Resources and Compliance	EDL are consistently performed on all RHS of PPSLR at offer of employment or volunteer opportunity; the EDL shall be done quarterly thereafter by VP of HR. New Hire Checklist audit will be conducted within the 1st week of every month by VP of HR and Compliance to ensure compliance .	
L1137 (Findings #11-19)	3. Ensure that ongoing staff education regarding infection control is consistently performed and documented. RHS of PPSLR shall review staff files to ensure that departmental training (.e.g. annual infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. annual infection control). Quality /Training Coordinator shall ensure the documentation is provided in employee/volunteer HR file. Vice President of Human Resources and Compliance will perform yearly audits on RHS of PPSLR on employee/volunteer files to ensure completion of yearly infection control training.	
L1137 (Findings #20-22)	4. Ensure orientation is consistently completed and documented. RHS of PPSLR shall review staff files to ensure that departmental training (.e.g. infection control) is completed on all employees and volunteers. Training will be provided to any employee that is missing department training.	4/30/16	Director of Surgical Services and Director of Quality, Training and Education	Director of Surgical Services and Quality and Training Coordinator shall review staff list and coordinate the time needed for staff/volunteer to complete the CAL training (e.g. infection control). Quality /Training Coordinator shall ensure the documentation is provided in	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
				employee/volunteer HR file. Vice President of Human Resources and Compliance will perform quarterly audits on RHS of PPSLR new employee/volunteer files to ensure completion of orientation training.	
L1153 (Findings #1 -17)	1. <u>Ensure medication orders are timed, dated and signed by ordering practitioner.</u> Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering practitioners and medications administrated to the patient are documented including dose, time and date and signed by the person administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering practitioner and all medications administered to the patient are documented including date, time and initials of nurse who is administering medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives. RHS of PPSLR shall train staff and ordering physicians on the updated policy.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	F1: Pharmaceutical Services Policy. F1: Pre-Printed Physician's Order Sheet F1: RHS of PPSLR Medication Administration Record(MAR)

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1153 (Findings #1 -17)	2. Ensure medication administered to patient are documented including dose, time timed, dated and signed by ordering practitioner. Updated existing PPSLR Policy titled: Pharmaceutical Services to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives. Plan to train staff on the updated policy.	5/6/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	F1: Pharmaceutical Services Policy. F1: Pre-Printed Physician's Order Sheet F1: RHS of PPSLR Medication Administration Record(MAR)
L1153 (Findings 1-17)	3. Ensure medical record documentation clearly provide staff direction for documentation and clinical judgement of pharmaceuticals to be timed, dated and signed by the person making the entry. Updated existing PPSLR Policy titled: "Pharmaceutical	5/6/16	Director of Surgical Services and Lead NP and Director of Quality,	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient	F1: Pharmaceutical Services Policy.

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
	Services" to include language that reflects and ensures that medication orders are timed, dated and signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. Revised existing RHS-PPSLR Standing orders to include specific dosing ranges and pain levels associate with each pain level dosing. Created a form titled: "RHS Patient Orders" to serve as an interim bridge to ensure medication orders are timed, dated, signed by the ordering physicians and medications administrated to the patient are documented including dose, time and initials of nurse who is administering the medication. RHS of PPSLR will consider capabilities of current EMR to meet the defined objectives.		Training and Education.	charts per week for 4 weeks. -Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management) Meeting Medical Director will provide training for ordering providers. Staff training will be conducted by Lead Nurse Practitioner and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	F1: Pre-Printed Physician's Order Sheet F1: RHS of PPSLR Medication Administration Record(MAR)
L1165 (Findings #1-11)	1. <u>Ensure policy for monitoring the stability and vital signs of patients during recovery is consistently adhered to and documented.</u> Update existing Pre-op &Post-op Patient Documentation from to include documentation of Aldrete Scoring System. Retraining of staff on RHS of PPSLR Recovery Area Care Policy and updated Pre-op &Post-op Patient Documentation form.	4/15/16	Director of Surgical Services and Lead NP and Director of Quality, Training and Education and VP of Patient Services.	Supervisory observation and monitoring compliance will be done through the current scheduled weekly audits conducted by Lead Nurse Practitioner. _ RHS Nurse Practitioner will conduct and document the random daily audits of 5 patient charts per week for 4 weeks. --Director of Surgical Services and Director of Quality, Training and Education will oversee and monitor the audit work plan. _The results of these audits will be reported to the CQRM (Clinical Quality Risk Management)	

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
				Meeting . Staff training will be conducted by Lead Nurse Practitioner , Nursing and Training Coordinator and Director of Quality, Training and Education on the updated Pharmaceutical Ordering and Administration and new form titled: "RHS of PPSLR Patient Orders" Staff sign-in attendance sheet will be submitted as evidence.	



STERILECHECK

Self-Contained Biological Indicator
(For use in Steam sterilization cycles)

Storage: 60-80°F (15-27°C), 30-70% relative humidity. Protect from freezing, sterilants, and light. Do not refrigerate.

Description: SterileCheck™ is intended for use in the monitoring of saturated Steam sterilization cycles. Each SterileCheck™ vial contains a spore disc inoculated with *Geobacillus stearothermophilus* (#7953) spores and a culture medium encased in a glass ampoule with a pH indicator. The acid production associated with growth, causes a change in color of the SterileCheck™ media to, or toward yellow to facilitate the detection of growth.

Frequency of Testing: For the greatest control of sterilized goods, we recommend that 2 or more SterileCheck™ biological indicators (BI) be included with every load.

Precautions: Do not use damaged units. Do not use SterileCheck™ after expiration date (see side of box). Do not use if control test does not change color to yellow. Since SterileCheck™ contains live cultures, units should be handled with care. Always wear gloves and safety glasses when removing units from the sterilizer and when activating the units.

Disposal: Prior to disposal or discard, sterilize by steam at 121°C for not less than 30 minutes (positive and control tests only).

Instructions for use:

a) ***Exposure:*** Place one or more SterileCheck™ units in a horizontal position in the most difficult-to-sterilize locations. Best practice recommends placing the BI in a PCD (Process Challenge Device). Run Cycle as you normally would. Remove BI(s) and verify that the chemical indicator on the vial label has changed color. **CAUTION:** After sterilization, handle unit with care: Contents of the ampoule are hot and under pressure. Failure to allow sufficient cooling time (10-15 minutes) may result in bursting of the ampoule. Always wear appropriate safety gear (gloves and safety glasses) when handling sterilized units.

b) **Activation/Crushing:** After the Biological Indicator has cooled, crush the media ampoule to mix the purple media with the spore strip at the base of the ampoule. This can be done by simply placing it inside incubator key-hole shaped port and moving the top towards the right to activate it. You will see the glass vial inside has been crushed. At this point, you may crush the Control Test as well. Place both in the incubator.

c) **Incubation:** Place the processed unit(s) and one unprocessed (control) unit in a vertical position in an incubator at: 55-60°C for 24 hours.

d) **Monitoring:** Begin monitoring the incubated BIs after 12-18 hours. Record observations. All positive BIs should be recorded. **Do not continue to incubate positive BIs.** Final negative results can be determined after 24 hours of incubation.

e) **Interpretation:**
Control: The control unit should exhibit turbidity and/or a color change to or toward yellow. If the control unit does not show signs of growth, consider the test invalid.
Test: A failed sterilization cycle is indicated by turbidity and/or a color change to or toward yellow. A test unit that retains its original color indicates that sterilization parameters have been met.

Americans United for Life

STERILECHECK

Self-Contained Biological Indicator
(For use in Steam sterilization cycles)

LOT S97604 **10-Mar-2018**

This lot of product meets the accepted performance criteria defined in the manufacturers' Quality Control Specifications for this product and where applicable, the recommended performance parameters in the USP and ANSI/AAMI/ISO/EN 11138-1 for use in Monitoring Steam processes.

Organism: *Geobacillus stearothermophilus* ATCC® 7953
SCBI Dimensions: 9 mm x 51 mm Inoculated Carrier Dimensions: 6 mm

Characteristic	Result
Mean Population	1.5×10^5 Colony Forming Units (CFUs)/unit
Steam D-Value (121°C)	2.3 Minutes
Steam Survival Time	7.4 Minutes
Steam Kill Time	21.1 Minutes
Steam D-Value (132°C)	0.20 Minutes
Steam Survival Time	0.64 Minutes
Steam Kill Time	1.83 Minutes
Steam D-Value (134°C)	0.13 Minutes
Steam Survival Time	0.42 Minutes
Steam Kill Time	1.19 Minutes
Steam z-value	10°C

*Populations determined after preliminary heat treatment.

The D values were determined using the fraction-negative or survivor curve methods. The D-value(s) are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results; therefore, should determine the suitability for their particular use. Survival/kill times were determined based on USP calculations. Z values may be utilized to extrapolate D values at temperatures other than 121°C.

Storage: 15-30°C, 30-80% relative humidity. Protect from light, toxic substances, sterilants and excessive heat and moisture.
Incubation Conditions: 58-62°C for 24 hours
Disposal: Sterilize/Autoclave by steam at 121°C for not less than 30 minutes, or incinerate (standard microbial waste; nonpathogenic species). Do not use after expiration date.

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 3, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***PoC Approval***

Dear Mary Kogut:

The Plan of Correction for the deficiencies cited as a result of the Licensure Survey Survey conducted on ***March 16, 2016*** has been received in our office and forwarded to the surveyor(s). We want you to know the surveyor(s) has approved your Plan of Correction as submitted.

Please retain this letter for your files.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 19, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Revisit Survey***

Dear Mary Kogut:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the revisit survey conducted on ***May 17, 2016*** in reference to the original survey of ***March 16, 2016*** in connection with the ***State Licensure*** requirements as they pertain to ambulatory surgical centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 05/17/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced state licensure revisit was conducted on 05/17/16. See below for findings:	{L 000}		
{L1137}	19 CSR 30-30.060(1)(B)(13) A personnel record shall be maintained A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs). This regulation is not met as evidenced by: Based on state statute review, policy review, record review, and interview, the facility failed to: - Perform criminal background checks (CBCs - completion of an inquiry to the Highway Patrol for criminal records available for disclosure to a provider, to determine an individual's criminal history) prior to hire for one (Staff U) of one new employee personnel files reviewed; and - Perform employee disqualification list (EDL) inquiries (to determine if the new employee was placed on the EDL list maintained by the Department of Health and Senior Services, regarding employment eligibility) prior to hire for one (Staff U) of one new employee personnel files reviewed. The Abortion Facility does an average of 380 cases per month. On the first day of the survey, there were 35 cases. Findings included: 1. Review of the Missouri Statute Chapter 660, showed CBCs were required by any provider	{L1137}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 05/17/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L1137}	Continued From page 1 pursuant to Section 660.317.1 (that included facilities licensed under Chapter 197 - Ambulatory Surgical Centers and Abortion Facilities) prior to allowing any person who had been hired as a full-time, part-time or temporary position, to have contact with any patient. 2. Review of the Missouri Statute Chapter 660, showed EDL checks were required by any provider pursuant to Section 660.315 (that included facilities licensed under Chapter 197 - Ambulatory Surgical Centers and Abortion Facilities) to determine employment eligibility. 3. Review of the facility's document titled, "Employee Manual," dated 07/13, showed: - The Vice President (VP) of Human Resources would be responsible for performing all "background checks" that are applicable under Federal, State and Planned Parenthood of America laws and requirements; and - All candidates prior to hire will have a criminal background check and Employee Disqualification List search completed prior to hire, per the Missouri Revised Statutes Chapter 660, Section 317. 4. Review of the personnel record for Staff U, Medical Assistant, showed: - Staff U was employed by the facility effective 05/02/16. - There was no record of a CBC in her personnel file. - There was a verification the EDL had been checked dated 05/17/16, the day of the survey. The facility failed to complete the CBC and EDL prior to hire to ensure employment eligibility. 5. During an interview of 05/17/16 at 12:10 PM, Staff L, VP of Human Resources and	{L1137}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 05/17/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L1137}	Continued From page 2 Compliance, stated that: - There was not a CBC in Staff U's personnel record. - She did not complete a CBC or EDL until the personnel record came back to her after the employee had completed their orientation. - She had not received the personnel file. - She failed to complete the CBC and EDL on Staff U prior to hire.	{L1137}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced state licensure revisit was conducted on 05/17/16. See below for findings:	{L 000}		
{L1137}	19 CSR 30-30.060(1)(B)(13) A personnel record shall be maintained A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs). This regulation is not met as evidenced by: Based on state statute review, policy review, record review, and interview, the facility failed to: - Perform criminal background checks (CBCs - completion of an inquiry to the Highway Patrol for criminal records available for disclosure to a provider, to determine an individual's criminal history) prior to hire for one (Staff U) of one new employee personnel files reviewed; and - Perform employee disqualification list (EDL) inquiries (to determine if the new employee was placed on the EDL list maintained by the Department of Health and Senior Services, regarding employment eligibility) prior to hire for one (Staff U) of one new employee personnel files reviewed. The Abortion Facility does an average of 380 cases per month. On the first day of the survey, there were 35 cases. Findings included: 1. Review of the Missouri Statute Chapter 660,	{L1137}		

RECEIVED MAY 26 2016

A	B	C	D	E	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 60 days from receipt)	Title of Person Responsible for Correction	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "D"	Evidence/ Exhibit Attachment Numbers or "N/A"
L 1137					
	All PPSLRSWMO Reproductive Health Services (RHS) candidates will have a criminal background check and Employee Disqualification List (EDL) search completed prior to hire per the Missouri Revised Statutes Chapter 660 Section 317. All RHS candidates will be given an employment application and Consent to request Criminal Background Check and Consumer Report and Investigation after an interview is completed. All RHS candidates for hire will submit completed application and CBC/Consumer Report release form to VP of HR and Compliance. VP of HR and Compliance will conduct CBC/EDL/Reference Checks, HHS-OIG, SAM and Missouri and Federal Sexual Offender checks prior to offer.	5/26/16	Vice President of Human Resources and Compliance	This process will be ensured by completion of the "RHS of PPSLR Prior to Offer Checklist" by the VP of HR and Compliance before formal offer of employment is made to a final candidate.	1.Background Checks and Investigations Policy 2. Consent to Request Consumer Report and Investigative Consumer Report Information 2. RHS of PPSLR Prior to Offer Checklist

Exhibit 1

BACKGROUND CHECKS AND INVESTIGATIONS POLICY

PPSLRSWMO recognizes the importance of maintaining a safe and productive workplace with honest, trustworthy, qualified, reliable and non-violent employees.For the benefit of all employees and PPSLRSWMO, in furthering these interests and enforcing PPSLRSWMO policies, PPSLRSWMO will perform, or request that third parties perform, "background checks" or other types of investigations.These background checks and investigations may be performed by PPSLRSWMO at its discretion.The Vice President of Human Resources and Compliance will be responsible for performing all "background checks" that are applicable under Federal, State and Planned Parenthood of America (PPFA) laws and requirements.

Background checks and investigations performed for PPSLRSWMO may include the use of consumer reporting agencies which may gather and report information to PPSLRSWMO in the form of consumer or investigative consumer reports. Such reports, if obtained, may contain, but are not limited to, information concerning an applicant's or employee's credit standing or worthiness, credit capacity, character or general reputation . The types of reports that may be requested from consumer reporting agencies under this policy include, but are not limited to, credit reports, criminal records checks, driving records, and/or summaries of educational and employment records and histories . The information contained in these reports may be obtained by a consumer reporting agency from private or public records sources or through personal interviews with an employee's co-workers, neighbors, friends, associates, current or former employers or other personal acquaintances .

Pursuant to this policy, PPSLRSWMO may request consumer reports, including records checks and investigative reports based on interviews, in connection with an individual's application for employment, or at any time during the course of an employee's employment with PPSLRSWMO, for purposes of evaluating their suitability for employment, promotion, reassignment or retention as an employee .

All PPSLRSWMO Reproductive Health Services (RHS) candidates prior to hire will have a criminal background check and Employee Disqualification List (EDL) search completed prior to hire per the Missouri Revised Statutes Chapter 660 Section 317 .

Employees are expected to cooperate fully with the background checks and investigations policy. Such cooperation includes, among other things, providing truthful and complete information in response to inquiries made by PPSLRSWMO or third party investigations during the course of investigations and providing appropriate written authorizations that may be required by law so that PPSLRSWMO may obtain complete investigation reports.Failure to cooperate in these checks or investigations, or any attempt to interfere with PPSLRSWMO attempts to obtain information, may result in disciplinary action, up to, and including, termination.

Exhibit 2

PLANNED PARENTHOOD OF THE ST LOUIS REGION AND SOUTHWEST MISSOURI
CONSENT TO REQUEST CONSUMER REPORT & INVESTIGATIVE CONSUMER REPORT INFORMATION

PLEASE TYPE OR PRINT Full Name

understand that Planned Parenthood of the St Louis Region and Southwest Missouri (PPSLRSWMO) will use **Sterling InfoSystems Inc., 1 State Street, New York, NY 10004, (877) 424-2457** to obtain a consumer report and/or investigative consumer report and educational verification as part of the hiring process. I also understand that if hired, to the extent permitted by law, PPSLRSWMO may obtain further Reports from STERLING so as to update, renew or extend my employment.

I understand **Sterling InfoSystems Inc.** (STERLING) investigation may include obtaining information regarding my credit background, bankruptcies, lawsuits, judgments, paid tax liens, unlawful detainer actions, failure to pay spousal or child support, accounts placed for collection, character, general reputation, personal characteristics and standard of living, education, driving record and criminal record, subject to any limitations imposed by applicable federal and state law. I understand such information may be obtained through direct or indirect contact with former employers, schools, financial institutions, landlords and public agencies or other persons who may have such knowledge. If an investigative consumer report is being requested, I understand such information may be obtained through any means, including but not limited to personal interviews with my acquaintances and/or associates or with others whom I am acquainted. I acknowledge receipt of the attached summary of my rights under the Fair Credit Reporting Act and, as required by law, any related state summary of rights (collectively "Summaries of Rights").

This consent will not affect my ability to question or dispute the accuracy of any information contained in a Report. I understand if PPSLRSWMO makes a conditional decision to disqualify me based all or in part on my Report, I will be provided with a copy of the Report and another copy of the Summaries of Rights, and if I disagree with the accuracy of the purported disqualifying information in the Report, I must notify PPSLRSWMO within five business days of my receipt of the Report that I am challenging the accuracy of such information with STERLING.

I hereby consent to this investigation and authorize PPSLRSWMO to procure a Report on my background.

In order to verify my identity for the purposes of Report preparation, I am voluntarily releasing my date of birth, social security number and the other information and fully understand that all employment decisions are based on legitimate non-discriminatory reasons.

The name, address and telephone number of the nearest unit of the consumer reporting agency designated to handle inquiries regarding the investigative consumer report is:

Sterling InfoSystems, Inc. | 1 State Street 24th Floor New York, NY 10014 | 877-424-2457 | or | 5750 West Oaks Boulevard, Ste. 100 Rocklin, CA 95765 | 888-889-5248 | or | 6111 Oak Tree Boulevard, Independence, OH 44131 | 800-853-3228
California, Connecticut, Maryland, Oregon, Vermont and Washington State Applicants Only (AS APPLICABLE): I further understand that COMPANY will not obtain information about my credit history, credit worthiness, credit standing, or credit capacity unless: (i) the information is required by law; (ii) I am seeking employment with a financial institution (California, Connecticut and Vermont only – in California the financial institution must be subject to Sections 6801-6809 of the U.S. Code and in Vermont it must be a financial institution as defined in 8 V.S.A.§ 11101(32) or a credit union as defined in 8 V.S.A. § 30101(5)); (iii) I am seeking employment with a financial institution that accepts deposits that are insured by a federal agency, or an affiliate or subsidiary of the financial institution or a credit union share guaranty corporation that is approved by the Maryland Commissioner of Financial Regulation or an entity or an affiliate of the entity that is registered as an investment advisor with the United States Securities and Exchange Commission (Maryland only); (iv) I am seeking employment in a position which involves access to confidential financial information (Vermont only); (v) I am seeking employment in a position which requires a financial fiduciary responsibility to the employer or a client of the employer, including the authority to issue payments, collect debts, transfer money, or enter into contracts (Vermont only); (vi) COMPANY can demonstrate that the information is a valid and reliable predictor of employee performance in the specific position being sought or held; (vii) I am seeking employment in a position that involves access to an employer's payroll information (Vermont only); (viii) **the information is substantially job related, and the bona fide reasons for using the information are disclosed to me in writing, (complete the question below)** (Connecticut, Maryland, Oregon and Washington only);(ix) I am seeking employment as a covered law enforcement officer, emergency medical personnel, firefighter police officer, peace officer or other law enforcement position (California, Oregon and Vermont only – in Oregon the police or peace officer position must be sought with a federally insured bank or credit union and in Vermont the law

enforcement officer position must be as defined in 20 V.S.A. § 2358, the emergency medical personnel must be as defined in 24 V.S.A. § 2651(6), and the firefighter position must be as defined in 20 V.S.A. § 3151(3)); (x) the COMPANY reasonably believes I have engaged in specific activity that constitutes a violation of law related to my employment (Connecticut only); (xi) I am seeking a position with the state Department of Justice (California only); (xii) I am seeking a position as an exempt managerial employee (California only); and/or (xiii)) I am seeking employment in a position (other than regular solicitation of credit card applications at a retail establishment) that involves regular access to all of the following personal information of any one person: bank or credit card account information, social security number, and date of birth,, I am seeking employment in a position that requires me to be a named signatory on the employer's bank or credit card or otherwise authorized to enter into financial contracts on behalf of the employer, I am seeking employment in a position that involves access to confidential or proprietary information of the Company or regular access to $10,000 or more in cash (California only).

Bona fide reasons why PPSLRSWMO considers credit information substantially job related (complete if this is the sole basis for obtaining credit information) or in California the COMPANY'S basis for the credit check.

The reason for running a credit report will be provided to me by my potential employer/employer on a separate document. **NY Applicants Only:** I also acknowledge that I have received the attached copy of Article 23A of New York's Correction Law. I further understand that I may request a copy of any investigative consumer report by contacting STERLING. I further understand that I will be advised if any further checks are requested and provided the name and address of the consumer reporting agency.

California Applicants and Residents: If I am applying for employment in California or reside in California, I understand I have the right to visually inspect the files concerning me maintained by an investigative consumer reporting agency during normal business hours and upon reasonable notice. The inspection can be done in person, and, if I appear in person and furnish proper identification; I am entitled to a copy of the file for a fee not to exceed the actual costs of duplication. I am entitled to be accompanied by one person of my choosing, who shall furnish reasonable identification. The inspection can also be done via certified mail if I make a written request, with proper identification, for copies to be sent to a specified addressee. I can also request a summary of the information to be provided by telephone if I make a written request, with proper identification for telephone disclosure, and the toll charge, if any, for the telephone call is prepaid by or directly charged to me. I further understand that the investigative consumer reporting agency shall provide trained personnel to explain to me any of the information furnished to me; I shall receive from the investigative consumer reporting agency a written explanation of any coded information contained in files maintained on me. "Proper identification" as used in this paragraph means information generally deemed sufficient,to identify a person, including documents such as a valid driver's license, social security account number, military identification card and credit cards. I understand that I can access the following website - http://www.sterlinginfosystems.com/privacy - to view STERLING'S privacy practices, including information with respect to STERLING'S preparation and processing of investigative consumer reports and guidance as to whether my personal information will be sent outside the United States or its territories.
Para informacion en Espanol, visite www.consumerfinance.gov/learnmore o escribe a la Consumer Financial Protection Bureau, 1700 G Street N.W., Washington, DC 20552.

A Summary of Your Rights Under the Fair Credit Reporting Act

The federal Fair Credit Reporting Act (FCRA) promotes the accuracy, fairness, and privacy of information in the files of consumer reporting agencies. There are many types of consumer reporting agencies, including credit bureaus and specialty agencies (such as agencies that sell information about check writing histories, medical records, and rental history records). Here is a summary of your major rights under the FCRA. For more information, including information about additional rights, go to www.consumerfinance.gov/learnmore or write to: Consumer Financial Protection Bureau, 1700 G Street N.W., Washington, DC 20552.

- **You must be told if information in your file has been used against you.** Anyone who uses a credit report or another type of consumer report to deny your application for credit, insurance, or employment - or to take another adverse action against you - must tell you, and must give you the name, address, and phone number of the agency that provided the information.

- **You have the right to know what is in your file.** You may request and obtain all the information about you in the files of a consumer-reporting agency (your "file disclosure"). You will be required to provide proper identification, which may include your Social Security number. In many cases, the disclosure will be free. You are entitled to a free file disclosure if:
  - A person has taken adverse action against you because of information in your credit report;
  - You are the victim of identify theft and place a fraud alert in your file;
  - Your file contains inaccurate information as a result of fraud;
  - You are on public assistance;
  - You are unemployed but expect to apply for employment within 60 days.

In addition, all consumers are entitled to one free disclosure every 12 months upon request from each nationwide credit bureau and from nationwide specialty consumer reporting agencies. See www.consumerfinance.gov/learnmore for additional information.

- **You have the right to ask for a credit score.** Credit scores are numerical summaries of your creditworthiness based on information from credit bureaus. You may request a credit score from consumer reporting agencies that create scores or distribute scores used in residential real property loans, but you will have to pay for it. In some mortgage transactions, you will receive credit score information for free from the mortgage lender.
- **You have the right to dispute incomplete or inaccurate information.** If you identify information in your file that is incomplete or inaccurate, and report it to the consumer-reporting agency, the agency must investigate unless your dispute is frivolous. See www.consumerfinance.gov/learnmore for an explanation of dispute procedures.
- **Consumer reporting agencies must correct or delete inaccurate, incomplete, or unverifiable information.** Inaccurate, incomplete or unverifiable information must be removed or corrected, usually within 30 days. However, a consumer reporting agency may continue to report information it has verified as accurate.
- **Consumer reporting agencies may not report outdated negative information.** In most cases, a consumer-reporting agency may not report negative information that is more than seven years old, or bankruptcies that are more than 10 years old.
- **Access to your file is limited.** A consumer-reporting agency may provide information about you only to people with a valid need -- usually to consider an application with a creditor, insurer, employer, landlord, or other business. The FCRA specifies those with a valid need for access.
- **You must give your consent for reports to be provided to employers.** A consumer-reporting agency may not give out information about you to your employer, or a potential employer, without your written consent given to the employer. Written consent generally is not required in the trucking industry. For more information, go to www.consumerfinance.gov/learnmore.
- **You may limit "prescreened" offers of credit and insurance you get based on information in your credit report.** Unsolicited "prescreened" offers for credit and insurance must include a toll-free phone number you can call if you choose to remove your name and address from the lists these offers are based on. You may opt-out with the nationwide credit bureaus at 1-888-567-8688.
- **You may seek damages from violators.** If a consumer reporting agency, or, in some cases, a user of consumer reports or a furnisher of information to a consumer reporting agency violates the FCRA, you may be able to sue in state or federal court.
- **Identity theft victims and active duty military personnel have additional rights.** For more information, visit www.consumerfinance.gov/learnmore.
- **States may enforce the FCRA, and many states have their own consumer reporting laws. In some cases, you may have more rights under state law. For more information, contact your state or local consumer protection agency or your state Attorney General. For information about your federal rights, contact:**

TYPE OF BUSINESS:	CONTACT:
1.a. Banks, savings associations, and credit unions with total assets of over $10 billion and their affiliates.	a. Bureau of Consumer Financial Protection 1700 G Street NW Washington, DC 20552
b. Such affiliates that are not banks, savings associations, or credit unions also should list, in addition to the Bureau:	b. Federal Trade Commission: Consumer Response Center - FCRA Washington, DC 20580 (877) 382-4357
2. To the extent not included in item 1 above:	
a. National banks, federal savings associations, and federal branches and federal agencies of foreign banks	a. Office of the Comptroller of the Currency Customer Assistance Group 1301 McKinney Street, Suite 3450 Houston, TX 77010-9050
b. State member banks, branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act	b. Federal Reserve Consumer Help Center P.O. Box 1200 Minneapolis, MN 55480
c. Nonmember Insured Banks, Insured State Branches of Foreign Banks, and insured state savings associations	c. FDIC Consumer Response Center 1100 Walnut Street, Box #11 Kansas City, MO 64106
d. Federal Credit Unions	d. National Credit Union Administration Office of Consumer Protection (OCP) Division of Consumer Compliance and Outreach (DCCO)

	1775 Duke Street Alexandria, VA 22314
3. Air carriers	Asst. General Counsel for Aviation Enforcement & Proceedings Department of Transportation 1200 New Jersey Avenue, SE Washington, DC 20590
4. Creditors Subject to Surface Transportation Board	Office of Proceedings, Surface Transportation Board Department of Transportation 395 E Street SW Washington, DC 20423
5. Creditors Subject to Packers and Stockyards Act	Nearest Packers and Stockyards Administration area supervisor
6. Small Business Investment Companies	Associate Deputy Administrator for Capital Access United States Small Business Administration 409 Third Street, SW, 8th Floor Washington, DC 20416
7. Brokers and Dealers	Securities and Exchange Commission 100 F St NE Washington, DC 20549
8. Federal Land Banks, Federal Land Bank Associations, Federal Intermediate Credit Banks, and Production Credit Associations	Farm Credit Administration 1501 Farm Credit Drive Mclean, VA 22102-5090
9. Retailers, Finance Companies, and All Other Creditors Not Listed Above	FTC Regional Office for region in which the creditor operates or Federal Trade Commission: Consumer Response Center - FCRA Washington, DC 20580 (877) 382-4357

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- **You have the right to know what is in your file.** You may request and obtain all the information about you in the files of a consumer-reporting agency (your "file disclosure"). You will be required to provide proper identification, which may include your Social Security number. In many cases, the disclosure will be free. You are entitled to a free file disclosure if:
  - A person has taken adverse action against you because of information in your credit report;
  - You are the victim of identify theft and place a fraud alert in your file;
  - Your file contains inaccurate information as a result of fraud;
  - You are on public assistance;
  - You are unemployed but expect to apply for employment within 60 days.

  In addition, all consumers are entitled to one free disclosure every 12 months upon request from each nationwide credit bureau and from nationwide specialty consumer reporting agencies. See www.consumerfinance.gov/learnmore for additional information.

- **You have the right to ask for a credit score.** Credit scores are numerical summaries of your creditworthiness based on information from credit bureaus. You may request a credit score from consumer reporting agencies that create scores or distribute scores used in residential real property loans, but you will have to pay for it. In some mortgage transactions, you will receive credit score information for free from the mortgage lender.

- **You have the right to dispute incomplete or inaccurate information.** If you identify information in your file that is incomplete or inaccurate, and report it to the consumer-reporting agency, the agency must investigate unless your dispute is frivolous. See www.consumerfinance.gov/learnmore for an explanation of dispute procedures.
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- **Identity theft victims and active duty military personnel have additional rights.** For more information, visit www.consumerfinance.gov/learnmore.
- **States may enforce the FCRA, and many states have their own consumer reporting laws. In some cases, you may have more rights under state law. For more information, contact your state or local consumer protection agency or your state Attorney General. For information about your federal rights, contact:**

TYPE OF BUSINESS:	CONTACT:
1.a. Banks, savings associations, and credit unions with total assets of over $10 billion and their affiliates.	a. Bureau of Consumer Financial Protection 1700 G Street NW Washington, DC 20552
b. Such affiliates that are not banks, savings associations, or credit unions also should list, in addition to the Bureau:	b. Federal Trade Commission: Consumer Response Center - FCRA Washington, DC 20580 (877) 382-4357
2. To the extent not included in item 1 above:	
a. National banks, federal savings associations, and federal branches and federal agencies of foreign banks	a. Office of the Comptroller of the Currency Customer Assistance Group 1301 McKinney Street, Suite 3450 Houston, TX 77010-9050
b. State member banks, branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act	b. Federal Reserve Consumer Help Center P.O. Box 1200 Minneapolis, MN 55480
c. Nonmember Insured Banks, Insured State Branches of Foreign Banks, and insured state savings associations	c. FDIC Consumer Response Center 1100 Walnut Street, Box #11 Kansas City, MO 64106
d. Federal Credit Unions	d. National Credit Union Administration Office of Consumer Protection (OCP) Division of Consumer Compliance and Outreach (DCCO) 1775 Duke Street Alexandria, VA 22314
3. Air carriers	Asst. General Counsel for Aviation Enforcement & Proceedings Department of Transportation 1200 New Jersey Avenue, SE Washington, DC 20590
4. Creditors Subject to Surface Transportation Board	Office of Proceedings, Surface Transportation Board Department of Transportation 395 E Street SW Washington, DC 20423

5. Creditors Subject to Packers and Stockyards Act	Nearest Packers and Stockyards Administration area supervisor
6. Small Business Investment Companies	Associate Deputy Administrator for Capital Access United States Small Business Administration 409 Third Street, SW, 8th Floor Washington, DC 20416
7. Brokers and Dealers	Securities and Exchange Commission 100 F St NE Washington, DC 20549
8. Federal Land Banks, Federal Land Bank Associations, Federal Intermediate Credit Banks, and Production Credit Associations	Farm Credit Administration 1501 Farm Credit Drive Mclean, VA 22102-5090
9. Retailers, Finance Companies, and All Other Creditors Not Listed Above	FTC Regional Office for region in which the creditor operates or Federal Trade Commission: Consumer Response Center - FCRA Washington, DC 20580 (877) 382-4357

I acknowledge receipt of the preceding "Summary of Rights" by checking this box. ☐

Name _____

Date _____

Americans United for Life

Exhibit 3

Planned Parenthood®
Care. No matter what.

Planned Parenthood of the St. Louis Region and Southwest Missouri

RHS OF PPSLR PRIOR TO OFFER CHECKLIST

Name:_____

☐ Print off two Job Descriptions

☐ Criminal Background Check - Sterling

☐ EDL – Missouri Employee disqualification list

☐HHS-OIG

☐SAM

☐Missouri Federal Sex Offender List

☐References

☐ Credentialing Forms if applicable: LCSW/RN/NP/MD

Completion date:_____

By:_____

Offer Accepted Date_____

Start Date_____

☐ Email to:
- Hiring Manager
- Human Resources Assistant
- Security
- Director of Surgical Services
- Director of Quality and Training
- Vice President of Patient services and Education

Americans United for Life

Staff U

Missouri Department of Health and Senior Services

Employee Disqualification List (EDL)

Date: 05/17/2016

Applicant's Social Security Number: [redacted]2094 Enter Clear

Message: SSN NOT FOUND ON EDL

Confirmation No: 201613800382

Name (first last)	Primary / Alias	Social Security Number

DHSS Home Senior Services

EDL Quarterly and Annual Reports

EDL Reports have moved. Please do the following:

1. Go to URL https://reportal.dhss.mo.gov/biportal/Login.aspx
2. Your User Name is the same as the one you used to get to this page.
3. Your password is set to uppercase first initial, uppercase last initial, and the last four digits of your SSN. You will be asked to change your password.
4. Once you are successfully logged in, click 'EDL' on the navigation area on the left side of the screen.
5. Click the desired report and it should be displayed for you.

***** Please note that your password to get to the reports and your password for the EDL website do not sync.**

For password issues contact us at 573-751-6388 or email support@health.mo.gov

For EDL issues contact us at (573) 522-1119, **or e-mail at** http://www.health.mo.gov/AskUs.html

Americans United for Life

Staff U

COMPLETE REPORT - CONSIDER

OrderID - 45784509

SterlingBackcheck

W[redacted], F[redacted]

[redacted]

PLANNED PARENTHOOD OF THE ST LOUIS REGION AND SOUTHWEST MISS (BILLCODE: RHS)
4251 FOREST PARK AVE
ST LOUIS, MO 63108

PHONE: 888.889.5248
DisputeResolution@sterlingbackcheck.com

*** INFORMATION IN THIS REPORT IS FOR ONLINE REVIEW ONLY ***

(USE THE **PRINT REPORT** FUNCTION FOR A FULLY COMPLIANT, REPRODUCIBLE REPORT)

REPORT SUMMARY

COMPONENT	IDENTIFIERS	STATUS	RESULT
Employee Credit Report	W[redacted]	Complete	[redacted]
Enhanced Nationwide Criminal Search	W[redacted]	Complete	[redacted]

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 27, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Licensure Survey***

Dear Mary Kogut:

The Plan of Correction is accepted in lieu of an onsite revisit. Please see attached results. This relates to the Licensure survey conducted on ***March 16, 2016*** and the revisit survey conducted on ***May 17, 2016***. Your facility is now in compliance with the ***Licensure*** requirements for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	R 05/26/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments The Plan of Correction is accepted in lieu of an onsite revisit. At this time, all deficiencies noted on the survey are corrected. The facility is now in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	{L 000}		

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

March 30, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00113026***

Dear Mary Kogut:

The results of the recent offsite complaint survey conducted on ***March 23, 2016*** through ***March 28, 2016*** indicate that your facility is in compliance with the State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 03/23/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An offsite investigation was conducted from 03/23/16 to 03/28/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00113026 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060	L 000		

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

May 27, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00114829***

Dear Mary Kogut:

The results of the recent unannounced allegation survey conducted at your facility on ***May 17, 2016*** and continued off-site until ***May 25, 2016*** indicate that your facility is in compliance with the State Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/25/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced allegation survey was conducted on 05/17/16, and continued off-site until 05/25/16, for complaint #MO00114829. The allegation was found to be unsubstantiated.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

July 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Compaint # MO00116700***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff regarding your facility on ***July 12, 2016*** indicate that your facility is in compliance with the Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 07/12/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted on 07/12/16 for the purpose of review of one complaint, #MO00116700, in relation to the Missouri Regulations for Abortion Facilities. The complaint was unsubstantiated and the facility was found to be in substantial compliance with 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

September 9, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00118398***

Dear Mary Kogut:

The results of the recent survey conducted at your facility from ***August 25, 2016*** through ***September 7, 2016*** indicate that your facility is in compliance with the State Licensure regulations for ambulatory surgical centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 09/07/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 08/25/16 through 09/07/16 for review of a complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00118398 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

October 14, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00119763***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***September 30, 2016*** and concluded on ***October 4, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 10/04/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 09/30/16 to 10/04/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00119763 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 9, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint MO00120615***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***November 7, 2016*** and concluded on ***November 8, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 11/08/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 11/07/16 to 11/08/16 for the purpose of review for 1 complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00120615 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 16, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00121121***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***November 14, 2016*** and concluded on ***November 15, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 11/15/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 11/14/16 to 11/15/16 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00121121 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

December 20, 2016

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey # MO00121661***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***December 7, 2016*** and concluded on ***December 19, 2016*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosure

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 12/19/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 12/07/16 to 12/19/16 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00121661 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 12, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint #MO00125526 Survey***

Dear Mary Kogut:

The results of the recent survey conducted on ***May 1, 2017*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/01/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 03/20/17 sporadically through 05/01/17 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00125526 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
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RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

May 12, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00126207 Survey***

Dear Mary Kogut:

The results of the recent survey conducted on ***May 1, 2017*** indicate that your facility is in compliance with the State Licensure regulations for abortion clinics in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/01/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 04/04/17 sporadically through 05/01/17 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00126207 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

August 17, 2017

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint # MO00131562***

Dear Mary Kogut:

The results of the recent allegation investigation survey conducted by our staff on ***August 14, 2017*** and concluded on ***August 15, 2017*** indicate that your facility is in compliance with the Licensure regulations for abortion facilities in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 08/15/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 08/14/17 through 08/15/17 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO 00131562 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Hoffmann, Tracy

From: Langston, John
Sent: Wednesday, December 20, 2017 8:12 AM
To: Hoffmann, Tracy
Subject: FW: complication plan approval - St. Louis facility
Attachments: RHS of PPSLRSWO Complication Plan.pdf; WU_PPSLR Agreement 2017.pdf

Importance: High

Print and then scan the email from Nikki as well as the attachments as one document to put on the O-drive as description "DHSS-approved complication plan for PP-St Louis to comply with SB5. Approved 10/23/2017."

From: Loethen, Nikki
Sent: Monday, October 23, 2017 4:29 PM
To: Hatfield, Charles (chuck.hatfield@stinson.com)
Subject: complication plan approval - St. Louis facility
Importance: High

This email serves as DHSS' written approval of the complication plan for the St. Louis facility (attached).

Nikki Loethen
General Counsel
Department of Health & Senior Services
912 Wildwood Drive
Jefferson City, MO 65102
Phone: 573.751.6005
Fax: 573.751.0247

From: Thomas, Janice [mailto:Janice.Thomas@ppslr.org]
Sent: Monday, October 23, 2017 2:05 PM
To: Loethen, Nikki; Langston, John
Cc: Kogut, Mary
Subject: SB5 Implementation for PPSLRSWMO

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John -

I understand from our attorneys that one outstanding item re the complication plan we previously submitted to DHSS in order to comply with S.B. 5 is that DHSS has requested a copy of the agreement between RHS and the on-call physicians referenced in the plan. I have attached that agreement.

Can you please confirm receipt of the agreement and that our plan has been approved. We have medication abortions scheduled for tomorrow and therefore would very much like to avoid an interruption of service for our patients' sake.

Please don't hesitate to give me or our attorneys' a call if you have any questions.

Thank you.

Janice Thomas
VP of Patient Services & Research

4251 Forest Park Avenue St. Louis, MO 63108
p: 314.531.7526 ext.341 | **f:** 314.531.9731 |
Janice.thomas@ppslr.org | www.plannedparenthood.org/stlouis

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REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION AND SOUTHWEST MISSOURI AND AFFILIATED CORPORATIONS

PATIENT SERVICES AND RESEARCH DEPARTMENTAL

PROCEDURE MANUAL

DEPARTMENT:	Patient Services and Education	**EFFECTIVE DATE:**	10/24/17
POLICY NUMBER:	PS.102	**NUMBER OF PAGES:**	2
POLICY:	On-Call Policy and Procedure RHS of PPSLR		

I. *PURPOSE/OBJECTIVE*

To ensure that the on-call program serves the needs of our patients; that our patients' concerns and complications are met in a timely and reliable manner; and to comply with Senate Bill 5 (HCS for SS for SB5, 99th General Assembly, Second Extraordinary Session (2017)), to be codified at Mo. Rev. Stat. 188.021.

II. *POLICY*

1) ***Care plans for potential abortion patient concerns or complications***
   a) RHS of PPSLR ensures all patients who have received abortion care at any of its health centers have access to an on-call clinician twenty-four hours/seven days (24/7) per week.
   b) At the time patients receive care at RHS of PPSLR, they receive patient education materials with education about signs and symptoms of potential complications and telephone numbers that can be used to reach an on-call nurse if a patient has questions or concerns. The written instructions shall state that a patient should call the health center during business hours, and provide a different telephone number to call after hours, to speak with a nurse about any questions, concerns or complications a patient may have or experience.
   c) During office hours, patients reach the main office number, which will forward patients' calls to the licensed nurse (APC, RN or LPN) on duty that day for triage and management. When the health center is closed the calls are directed to an answering service that forwards any calls to the licensed nurse (APC, RN or LPN) on-call after-hours for triage and management.
   d) Both during and after office hours the on-call nurse will personally assess the patient's concerns and complications in accordance with established protocols.
   e) The on-call clinician has access to a supervising/back-up OB/GYN who is on call and available for further consultation, when necessary. The on-call nurse will have access to the schedule of the backup OB/GYN physician on call.
   f) If the on-call clinician makes the determination that the patient should be assessed in person, but the patient does not need emergency care, the on-call nurse should instruct the patient to return to a RHS health center. Similarly, if the after-hours on-call nurse believes a patient should receive an in-person assessment and that it is appropriate to wait, the clinician should instruct the patient to return to a RHS health center during office hours.
   g) In the event that the on-call nurse and/or the backup OB/GYN physician on call believes it is not in the patient's best interest or it would not be in accordance with the standard of care for the

patient to return to the health center during office hours, the patient will be instructed to go to her nearest emergency room.

h) The patient must be instructed to take with her to the emergency room the written post-procedure instructions that were previously provided to her, which explain that the patient received abortion care and provide the telephone numbers to reach an RHS on-call nurse. The patient must also be instructed to call the on-call nurse once she arrives at the emergency room.

i) The on-call nurse must not, as a matter of course, call the emergency room in advance without the patient's consent in order to protect her confidentiality and privacy, as the patient may decide to go to a different hospital for a variety of reasons (financial, insurance, concerns about confidentiality).

j) Once the patient arrives at the emergency room, she or, with the permission of the patient, the attending physician or other clinician managing her care should call the RHS clinician in order to brief the attending physician or other clinician managing the patient's care.

k) The on-call clinician must follow up with any patient who was assessed and determined to need follow-up care. The follow-up call shall be documented in the patients' medical record .

2) ***Documentation of Calls Received by On-Call Nurse***

a) ALL calls are initially managed by a licensed nurse (APC, RN or LPN) at RHS of PPSLR

b) ALL calls must be documented in patients record medical record

c) Call received during office hours shall be entered into the patients' medical record, immediately, if possible.

d) Ongoing issues/concerns that develop during the business day must be communicated to the afterhours on-call nurse, in the event, client calls the after-hours answering service later.

e) After–hours calls must be documented promptly after the call, preferably by noon the next business day in patients' medical record.

f) On-call nurse shall review the patients' medical record for all current and prior calls /visits relative to that patient prior to documenting the call e.

g) Hand-off Communication is required from off–going on-call nurse to on-coming on-call nurse. This communication should include: unresolved patient issues.

3) Written Agreement for OB/GYN Coverage for Complications

a) RHS of PPSLR has a written coverage agreement with the Washington University School of Medicine (WUSM), Department of Obstetrics and Gynecology

b) The members of the Division of Family Planning at the WUSM Department of Obstetrics and Gynecology, where the Medical Director is on staff, primarily serve as the physician backup for RHS' abortion patients 24/7.

c) All members of this division are board-certified or board-eligible OB/GYN physicians

d) If all the members of the division are unavailable (i.e. out of town for an academic conference), another member of the WUSM Department of Obstetrics and Gynecology, who is board-certified or board-eligible OB/GYN, who is the attending on call for department will serve as the backup

e) A rotation of the physician on-call is set in advance and communicated to RHS of PPSLR nursing staff on a regular basis.

Washington University in St. Louis
SCHOOL OF MEDICINE

George A. Macones, M.D., M.S.C.E.
Mitchell and Elaine Yanow Professor and Head
Department of Obstetrics and Gynecology

October 20, 2017

Washington University School of Medicine
Department of Obstetrics and Gynecology
660 S. Euclid Ave., Campus Box 8064
St. Louis, MO 63110

This letter updates the continued agreement between Planned Parenthood of the St. Louis Region and Southwest Missouri and Washington University School of Medicine, Department of Obstetrics and Gynecology for back up services, complication follow up, and emergency treatment for our abortion care patients.

The OB/GYN department will provide back-up services for Reproductive Health Services of Planned Parenthood of the St. Louis Region's surgical and medication abortion patients. An on-call physician in the department who is a board-certified or board-eligible OB/GYN will be available 24/7 for consultation when necessary for patients who contact Reproductive Health Services of Planned Parenthood of the St. Louis Region with potential complications related to an abortion for which consultation is warranted. The department will provide follow up care for patients who present at the hospital or are transferred for emergency treatment resulting from abortion complications.

The original agreement began on May 1 1996. This is a continuation of the agreement.

George A. Macones, M.D. M.S.C.E.
Mitchell and Elaine Yanow Professor and Head
Department of Obstetrics and Gynecology

David L. Eisenberg, M.D., M.P.H.
Medical Director
Planned Parenthood of the St. Louis Region and Southwest Missouri and
Reproductive Health Services of Planned Parenthood of the St. Louis Region

Mary M. Kogut
President and CEO
Planned Parenthood of the St. Louis Region and Southwest Missouri and
Reproductive Health Services of Planned Parenthood of the St. Louis Region

Americans United for Life

Washington University School of Medicine at Washington University Medical Center, Campus Box 8064,
4911 Barnes-Jewish Hospital Plaza, St. Louis, Missouri 63110-1094, (314) 362-7139, FAX: (314) 362-0041,
maconesg@wustl.edu

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 03/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	**4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An investigation was conducted from 03/06/18 sporadically through 03/19/18 for the purpose of review for one complaint in relation to the Missouri Regulations for Abortion Facilities. Complaint #MO00140153 was found to be unsubstantiated with no deficiencies. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

March 21, 2018

Mary Kogut
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint #MO00140153***

Dear Mary Kogut:

The results of the recent survey conducted at your facility on ***March 19, 2018*** indicate that your facility is in compliance with the State Licensure regulations for abortion facilities.
Please retain this material for your own records.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711
Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

June 18, 2018

Mary M. Kogut
President and CEO
Reproductive Health Services of Planned Parenthood of the St Louis Region (A001)
4251 Forest Park Avenue
St Louis MO 63108

Dear Ms. Kogut:

This is in response to your letter requesting a waiver of the regulatory requirement for a pelvic exam prior to a medical abortion (19 CSR 30-30.060(2)(D)). The department has considered the request and determined that the requirement is proper. Additionally, there is no provision in the abortion facility regulations that authorizes the department to grant waivers of this requirement. The 2010 settlement agreement between DHSS and Planned Parenthood exempts only the Kansas City location from this requirement. Therefore, the request is denied.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

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Planned Parenthood®
Care. No matter what.

Reproductive Health Services of Planned Parenthood of the St. Louis Region

4251 Forest Park Avenue
St. Louis, MO 63108

p: 314.531.7526 | f: 314.531.9730
www.plannedparenthood.org/stlouis

May 23, 2018

Dr. Randall Williams
Missouri Department of Health and Senior Services
912 Wildwood
Jefferson City, MO 65102-0570

Dear Dr. Williams,

On behalf of Reproductive Health Services of Planned Parenthood of the St Louis Region (RHS), we are applying for a waiver of the state mandated pelvic exam required prior to medication abortions.

The health and safety of women is our mandate. The most recognized national medical expects on women's health and abortion, The American College of Obstetrics and Gynecology (ACOG), Planned Parenthood Federation of America and the National Abortion Federation, consider a pelvic exam prior to a medication abortion medically unnecessary except in specific circumstances. These experts have established the standards of care based on an expansive review of care delivered across a variety of settings, circumstances, and involving millions of patients. In addition, recently the National Academies of Sciences, Engineering and Medicine published a comprehensive report on the safety and quality of abortion care in the U.S. which confirmed that the clinical assessments required prior to medication abortion do not include a pelvic exam for all women.

The state of Missouri, in dictating the policy of a pelvic exam prior to medication abortion for every patient, regardless of her individual, medical and personal history, goes against an evidence-based approach to medical care, potentially violates consent practices, and forces women to submit to an intrusive medical exam that is not necessary to ensure women's health and safety. With the recent public recognition of the assaults perpetrated by Dr. Larry Nassar under the guise of "medical care" and the MeToo movement, stressing the protection of women's bodily integrity is more important than ever. Yet, our physicians are forced to choose between adhering to a requirement that involves performing a medically unnecessary and invasive state-mandated exam on their patients or denying women their desired medication abortion. The Department's historic lack of enforcement of this requirement makes clear that it is not necessary for the health and safety of women. In prior annual inspections by the Department, we have never been issued a citation on this by the state surveyors. Indeed, email communications between the State surveyors indicate they accepted that pelvic examinations were unnecessary at RHS because sonograms are performed for every patient. In addition, we

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are aware that the Planned Parenthood affiliate that provides abortions in Kansas City, Missouri, is exempted from having to perform pelvic exams prior to a medication abortion when such an exam is not medically indicated. Moreover, any hospital that provides a medication abortion to a woman does not need to abide by this requirement as it is a standard specific only to abortion facilities. Thus, there is no basis to conclude that the pelvic exam requirement is necessary for women's health. On the contrary, the requirement only serves to place an additional burden on abortion access in Missouri.

Recently, we submitted a plan of correction for our most recent survey that indicated we would do pelvic exams prior to medication abortion. However, our physicians do not feel they can ethically require women to undergo a pelvic exam prior to medication abortion, unless such exam is medically indicated based on specific patient-level issues. As almost 40% of all abortions in Missouri are now medication abortion, this one unnecessary mandate will severely limit abortion services in Missouri. Losing the option of medication abortion in Missouri will negatively impact the health and safety of women by forcing women to consider surgical options, postpone their procedure to later gestational ages, or not access abortion care at all.

We implore you to reverse this decision, or grant us a waiver such that this requirement will not be enforced for women choosing medication abortion. Attached to this letter is supporting documentation for our request. Thank you for your attention to this critical matter. We are also available at any time for a discussion of this important matter.

Sincerely,

Mary M. Kogut
President and CEO

Dr. David Eisenberg, MD, MPH, FACOG
Medical Director

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Violation of Patient Consent Due to State Mandate

Even if a patient would "consent" to a pelvic exam prior to a medication abortion, a consent given under coercion is not valid. Performing an unnecessary pelvic examination on a patient in violation of our providers' clinical judgment and a patient's right to refuse is unconscionable. No clinic and no doctor should be forced to comply with a standard that clearly violates the standard of care and violates women's rights to a constitutionally protected procedure.

Violation of Patient Bodily Integrity Due to State Mandate

The attached journal article is about mandating a pelvic exam in order to receive birth control pills. Although the state is mandating a pelvic exam in order to receive a medication abortion, the argument is the same. A pelvic examination is invasive and can be difficult for patients. In particular, victims of rape, or women who have experienced sexual abuse or molestation or other trauma, may want to avoid further trauma from having instruments or a clinician's fingers placed in their vagina, such as during a pelvic exam. Women with such histories often choose medication abortion precisely to avoid having instruments placed in their vagina.
There are serious ethical concerns with requiring patients to undergo intrusive examinations in situations where they are not medically necessary, and women should be able to make their own informed decisions about whether to undergo additional screening procedures that are not medically necessary for the service they are seeking.

Pelvic Exam Prior to Medication Abortion is Not the Acceptable National Standard of Care

A pelvic examination is an intrusive procedure that is not medically necessary for every patient prior to a medication abortion, nor is it part of the accepted standard of care to perform a pelvic examination on every patient seeking a medication abortion. This one-size-fits-all mandate does not consider whether such an exam is medically indicated and is thus overly broad.

The most significant adverse concern is to rule out an ectopic pregnancy prior to medication abortion. RHS, in general, performs an ultrasound prior to administering the mifepristone. This is a more sensitive and precise way to determine pregnancy size and location in the early stages of gestation.

PPFA and the National Abortion Federation, the two national organizations that accredit abortion providers, do not require a pelvic exam be performed before every medication abortion. (2018 Clinical Policy Guidelines for Abortion Care, National Abortion Federation, p. 17-19.) Similarly, ACOG, the leading national organization of obstetricians and gynecologists, issues guidelines for medication abortion. These guidelines also do not require routine pelvic exams for medication abortion patients who have had an ultrasound. (Practice Bulletin: Medical Management of First-Trimester Abortion, The American College of Obstetricians and Gynecologists, Number 143, March 2014, Reaffirmed 2016.) Instead, the standard of care is to provide a pelvic examination to patients prior to a medication abortion **only** when such an examination is indicated, for example if the patient is experiencing vaginal bleeding or abdominal/pelvic pain.

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Missouri DHSS Acknowledged, Approved, and Accepted the Practice of No Pelvic Exams For 18 Years Prior to 2018. DHSS Has an Inconsistent Policy on this Requirement

DHSS's historical practices have recognized that these examinations are not medically necessary. As the attached documents show, DHSS has explicitly overlooked this issue in prior inspections of RHS's facility, and has done so because RHS conducts an ultrasound examination for every patient seeking an abortion, including those seeking a medication abortion, rendering a pelvic examination medically unnecessary. See attached documents, produced in discovery in Comprehensive Health v. Williams, No. 2:17-cv-4207 (W.D. Mo.).

In addition, RHS is aware that DHSS has waived the pelvic examination requirement for the abortion provider in Kansas City, which provides only medication abortions. And, hospitals that provide abortions are not subjected to this requirement and do not perform a pelvic examination prior to medication abortion. There cannot possibly be a medical justification for requiring women who obtain medication abortions in a St. Louis abortion facility to be subjected to an intrusive and medically unnecessary examination that women in Kansas City or a hospital, receiving the same medical service, are permitted to forgo. See attached Settlement Agreement.

Impact of This Requirement

Our providers are the highest trained in our state in the provision of abortion care. They utilize evidence-based standards and guidelines in addition to years of actual hands on training, experience and skills. In their judgement, performing an unnecessary, invasive, exam on a woman who has no ability to refuse it is unethical and morally reprehensible, going against their training and values as providers. In their medical and ethical judgement, our providers believe only those women whose medical history dictates the need for a pelvic exam, should be offered medication abortion. To not be able to offer it to women whose history does not indicate the need for a pelvic exam means a further burden on women accessing their constitutionally protected right to an abortion.

To expect women to choose a surgical procedure instead is wrong. To expect women to have to drive a further distance or leave the state of Missouri to obtain a medication abortion is wrong. This decision does not further women's health and safety.

We urge the department to reverse this requirement or to grant a waiver to Reproductive Health Services. Thank you.

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Message

From: Maine, Karen [/O=MISSOURI STATE GOVERNMENT/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=MAINEK]
Sent: 8/17/2017 4:48:44 PM
To: Langston, John [/O=MISSOURI STATE GOVERNMENT/OU=First Administrative Group/cn=Recipients/cn=LangsJ75607050]; Cummins, Todd [/O=MISSOURI STATE GOVERNMENT/OU=First Administrative Group/cn=Recipients/cn=CummiT]; Degreef, Marjorie [/O=MISSOURI STATE GOVERNMENT/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Degrem]
Subject: FW: 188.025 law requiring abortions over 16 weeks in hospital ruled unconst

I thought I had emailed someone from CLIA about the hematocrit vs. hemoglobin and the accuracy of their statement but can't find it. I have no idea now who was in CLIA 2 ½ years ago. So the rule is 1184: The following laboratory procedures shall be performed on every abortion patient: hematocrit; urinalysis, including pregnancy test; and Rh typing. I'll see what I can find out from a current CLIA person about hematocrit vs. hemoglobin.

From: Maine, Karen
Sent: Tuesday, March 31, 2015 7:06 PM
To: Langston, John; Cummins, Todd; Jordan, Alice
Cc: Czuba, Denise
Subject: RE: 188.025 law requiring abortions over 16 weeks in hospital ruled unconst

Thanks again for your help with this while we were on-site. The president/CEO knew the answer and COULDN'T BELIEVE we don't have those updates when we survey. We found other concerns (go figure). The rules say that the pregnancy has to be confirmed by ultrasound AND lab results. Those rules were written way back when ultrasound images were not near what they are today. We decided to disregard the rule on this one because what's the point of doing a pregnancy test if you can clearly see the image of a baby in ultrasound. Also, these rules were written before the "abortion pill." The facility did not do pelvic exams prior to the abortion and we overlooked that rule as well. Anyone disagree?

Then there is the rule to do a hematocrit on all patients prior to the abortion. The facility has reportedly never done hematocrits, only a hemoglobin because it's "more accurate." Oh, and why was this never brought up on a previous survey? Anyway, we exited saying that we were still getting clarification on that issue.

From: Langston, John
Sent: Tuesday, March 31, 2015 11:18 AM
To: Cummins, Todd; Maine, Karen; Jordan, Alice
Cc: Czuba, Denise
Subject: 188.025 law requiring abortions over 16 weeks in hospital ruled unconst

I've copied this to the I-Drive. Yes, it would be nice if there were a mention of this in the Mo laws website itself. Re: **188.025 RSMo. Abortions past 16 weeks only in a hospital?**

Hospital required, when.

188.025. Every abortion performed at sixteen weeks gestational age or later shall be performed in a hospital.

(L. 1974 H.B. 1211 § 4, A.L. 1979 H.B. 523, et al., A.L. 1986 H.B. 1596)

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That's the law itself. Then, if you go looking, you find court cases about the law, where this portion was found unconstitutional:

(1981) A requirement that second trimester dilation and evacuation abortions be performed in hospital is unconstitutional because the court found that an outpatient procedure was no more dangerous to maternal health than a hospital procedure while being far less expensive. Planned Parenthood v. Ashcroft (8th Cir.), 664 F.2d 687.

(1983) The second-trimester hospitalization requirement of this statute is unconstitutional because it unreasonably infringes upon a woman's constitutional right to obtain an abortion. Planned Parenthood of Kansas City, Mo. v. Ashcroft, 103 S.Ct. 2517.

(1987) United States District Court for the Western District of Missouri Central Division, on March 17, 1987, held that section 188.025 was unconstitutional and the state was permanently enjoined from enforcing this provision. Reproductive Health Services v. William L. Webster, 655 F.Supp. 1300 (W.D. Mo.).

(1988) United States Court of Appeals for the Eighth Circuit affirmed the district court's judgment that this section is unconstitutional. Reproductive Health Services v. William L. Webster, 851 F.2d 1071 (8th Cir.).

If you want a more lengthy write up/analysis on this:
http://openjurist.org/664/f2d/687/planned-parenthood-association-of-kansas-city-missouri-inc-v-ashcroft

http://www.priestsforlife.org/government/supremecourt/8306plannedparenthoodofkansascityvashcroft.htm

https://law.resource.org/pub/us/case/reporter/F2/664/664.F2d.687.80-1530.80-1130.html

John Langston, Administrator

Bureau of Ambulatory Care
Department of Health and Senior Services
PO Box 570, 3418 Knipp Drive
Jefferson City, Missouri 65102
Phone: (573) 751-6083
Fax: (573) 751-6158

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Release and Settlement Agreement

This Release and Settlement Agreement is made and executed by and between Planned Parenthood of Kansas and Mid-Missouri, Inc., (hereinafter referred to as "PPKM"), the Missouri Department of Health and Senior Services, (hereinafter referred to as "DHSS"), Margaret Donnelly, in her official capacity as the Director of DHSS (hereinafter referred to as "Donnelly"), Chris Koster, in his official capacity as Attorney General of the State of Missouri (hereinafter referred to as "Koster"), James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, Missouri (hereinafter referred to as "Kanatzar"), and Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, Missouri (hereinafter referred to as "Knight"), (DHSS, Donnelly, Koster, Kanatzar, and Knight will hereinafter be referred to collectively as "Defendants"; PPKM and Defendants will hereinafter be referred to collectively as the "Parties.") The Parties enter into this agreement through their respective lawyers.

For due and good consideration recited herein, the Parties agree and state as follows:

1. **Plaintiff.** PPKM is the Plaintiff in lawsuits styled (1) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Jane Drummond, et al.*, No. 07-4164-CV-C-ODS, in the United States District Court for the Western District of Missouri, Central Division; (2) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00463, filed in the Cole County Circuit Court; and (3) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00276, filed in the Cole County Circuit Court.

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(These lawsuits will hereinafter be referred to collectively as the "Lawsuits.")

2. **Defendants.** Defendants are named as the defendants in the Lawsuits.

3. **Scope of Agreement.** This Agreement embodies the entire agreement and understanding of the Parties with respect to the subject matter contained herein. The Parties hereby declare and represent that no promise, inducement, or agreement not herein expressed has been made, and the Parties acknowledge that the terms and conditions of this Agreement are contractual and not a mere recital.

4. **Non-Admission.** No actions taken by the Parties, or any of them, either previously or in connection with this Agreement shall be deemed or construed to be an admission of the truth or falsity of any matter pertaining to any claim or defense alleged in the pleadings filed on behalf of the Parties in the Lawsuits, or an acknowledgment by any of the Parties of any liability to the other parties or to any person for any other claim, demand, or action, all liability being expressly denied by the Parties.

5. **Consideration.** In consideration for (1) PPKM's dismissal of the Lawsuits; (2) PPKM's release of claims as set forth in paragraph 10 of this Agreement; (3) PPKM's agreement to complete structural changes at the Columbia Center and to otherwise comply with 19 CSR 30-30.070(2), as set out in paragraph 6 of this Agreement; and (4) PPKM's agreement that the Brous Center will comply with certain provisions of 19 CSR 30-30.050 and 19 CSR 30-30.060, as set out in paragraph 7 of this Agreement, the Defendants agree that DHSS will approve the Columbia Center and the Brous Center for licensure as abortion facilities.

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6. **Modifications of the Columbia Center.** PPKM agrees to make modifications to its facility located in Columbia, Missouri ("Columbia Center") as set out in the attached Addendum A. PPKM anticipates being able to begin construction within nine months of the date that this Agreement is finally signed by all the parties and completing construction within sixteen months from the date this Agreement is finally signed by all the parties, and agrees that while certain factors relevant to this timing (such as the DHSS's approval of its architectural drawings and sprinkler plans) are not under PPKM's control, it will make a good-faith effort to comply with these time frames.

PPKM agrees that it will submit architectural drawings showing the modifications to be made, as set out in Addendum A, to DHSS before work begins at the Columbia Center, including the agreed upon modifications in the sterilization and soiled rooms, and the sprinkler plans. PPKM agrees that DHSS shall be granted entry onto the Columbia Center premises for a mid-construction progress inspection. DHSS agrees that it will give PPKM at least 7 days prior notice of the proposed date for its progress inspection, which shall commence at an agreed upon date and time convenient to both parties. DHSS will be available for follow up questions and approval of specific construction or design questions as they arise and will endeavor to provide prompt responses to the Columbia Center during the construction and pre-approval phases.

PPKM agrees to permit DHSS to conduct a final inspection of the Columbia Center within 2 weeks of the completion of the structural modifications set out in Addendum A and before an abortion facility license is issued to ensure that the modifications at the Columbia

Center have been completed as agreed and also to ensure that the Columbia Center is also in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A. If this inspection reveals that the modification set out in Addendum A have not been completed as agreed, or that the Columbia Center is not in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, PPKM agrees that it will make a good-faith effort to complete the remaining work needed for the Columbia Center to complete the modifications set out in Addendum A, and to be in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, within six weeks.

DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the requirements of 19 CSR 30-30.070(2) except as specifically set forth in Addendum A, and will not require changes not set forth in Addendum A unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to no longer be in compliance with those requirements.

7. **Brous Center.** PPKM will comply with the procedural, operational, and management requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, at its Brous Center location. Modifications to certain requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060 that will apply to the Brous Center are set forth in Addendum B.

PPKM agrees to permit an inspection of the Brous Center before an abortion facility license is issued to ensure that the Brous Center is in compliance with the requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, as modified by Addendum B.

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The Parties acknowledge that the Brous Center currently does not perform surgical abortions. If the Brous Center at a future time wishes to provide surgical abortion services, PPKM will notify Defendants' counsel. PPKM understands that the performance of surgical abortions at the Brous Center would constitute a material change that would require the Brous Center to comply with additional regulations.

8. **Provision of Services.** It is the intention of the Parties and Defendants that the Columbia Center may continue providing abortion services throughout the process of preparing for and completing the modifications described in paragraph 6, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process. It is the intention of the Parties and Defendants that the Brous Center may continue providing medication abortion services during the abortion facility license application process, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process.

9. **Dismissal of the Lawsuits.** Upon payment of the fees and expenses set forth in Paragraph 12 of this Agreement, the Parties shall also execute the following Stipulations of Prejudicial Dismissal: (a) a Stipulation of Prejudicial Dismissal pursuant to Fed. R. Civ. P. 41(a)(1)(ii), to be filed the federal lawsuit identified in paragraph 1 of this Agreement, dismissing with prejudice PPKM's claims in their entirety; and (b) Stipulations of Prejudicial Dismissal pursuant to Mo. R. Civ. P. 67.02, to be filed in the state lawsuits identified in paragraph 1 of this Agreement dismissing with prejudice all claims raised in those lawsuits.

10. **Release.** PPKM does hereby release, acquit, and forever discharge the

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Defendants, the State of Missouri, and any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, of all and from any and all liability, claims, actions, causes of action, demands, rights, damages, costs, interest, loss of service, expenses, and compensation whatsoever, whether or not now known or contemplated, which PPKM now has, or which may hereafter accrue, against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on or arising out of the allegations in the Lawsuits relating to the licensure of the Columbia and Brous Centers. PPKM specifically acknowledges that it is forever barred from filing suit against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on any claim based on or arising out of the allegations in the Lawsuits relating to licensure of the Columbia and Brous Centers.

11. **Full Consideration.** PPKM acknowledges that the consideration described in paragraph 5 of this Agreement is all that it or its representatives are ever to receive from the State of Missouri, the Defendants, or any person or entity related to them whatsoever, for the settlement described in this Agreement, whether in settlement of PPKM's claims for damages, attorney's fees, costs, or other claims which were or could have been asserted in the Lawsuits.

12. **Attorney's Fees, Costs and Expenses.** In exchange for payment of $80,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and the regulations implementing that law to the

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Columbia Center, and payment of $65,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and regulations implementing that law to the Brous Center in the federal lawsuit, PPKM hereby waives any remaining claim it might have against the State of Missouri, the Defendants in the Lawsuits, or any current or former employee, agent, agency, actor, or contractor of the State for attorney's fees, expenses, or costs, pursuant to 42 U.S.C. § 1988, or any other statute, rule, or other provision of law which is or may be in any way applicable hereto. The payment of $145,000.00 will be issued to Plaintiff's counsel by June 30, 2010.

13. **Court Costs.** The Parties will bear their own court costs.

14. **Non-Assignment.** PPKM hereby represents, acknowledges, and warrants that it has not at any time heretofore assigned to any other person or entity all or any portion of any claim or potential claim whatsoever that it may have, or may have had, against the Defendants, the State of Missouri, or any person or entity whatsoever based on or arising out of the allegations contained in the Lawsuits.

15. **Binding Effect.** The persons signing this Agreement represent that they have read this Agreement and fully understand its provisions. The signatories of the Parties declare that they are of legal age and that they have relied solely upon their own judgment without influence of anyone in making this Agreement. This Agreement shall be binding upon, and inure to the benefit of the heirs, personal representatives, successors, and assigns of the Parties.

16. **Preparation of Documents.** This Agreement is the joint work product of the

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Parties and, in the event of any ambiguity herein, no inference shall be drawn against a party by reason of document preparation.

17. **Further Execution.** Each party hereto shall execute any and all documents as are necessary or desirable to consummate the transactions contemplated hereby.

18. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be deemed executed as of the date the Agreement was finally signed by the Parties below.

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PLANNED PARENTHOOD OF KANSAS
AND MID-MISSOURI, INC.

By: _____

Title: Attorney for PPKM

STATE OF New York)
) ss
COUNTY OF New York)

Before me, a notary public for the State of New York, personally appeared Jonnfer Sandman, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Planned Parenthood of Kansas and Mid-Missouri, Inc., and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18 day of May, 2010.

_____
Notary Public

My commission expires on 11/9/13.

DARA KLASSEL
NOTARY PUBLIC-STATE OF NEW YORK
No. 02KL4913955
Qualified in New York County
My Commission Expires 11/9/13

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MISSOURI DEPARTMENT OF HEALTH
AND SENIOR SERVICES

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF Missouri)
) ss
COUNTY OF Cole)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for the Missouri Department of Health and Senior Services with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08600003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

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MARGARET DONNELLY, in her official capacity as Director, Missouri Department of Health and Senior Services

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Margaret Donnelly with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Margaret Donnelly, in her official capacity as Director of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08500003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

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CHRIS KOSTER, in his official capacity as
Attorney General of Missouri

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Chris Koster with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Chris Koster, in his official capacity as Attorney General of Missouri, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number 08440003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

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JAMES KANATZAR, in his official capacity
as Prosecuting Attorney of Jackson County

By: James F. Kanatzar

Title: Prosecuting Attorney

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared James F. Kanatzar, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 26 day of May, 2010.

Michael A. Wells
Notary Public

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

MICHAEL A. WELLS
My Commission Expires
September 24, 2012
Jackson County
Commission #08409225

My commission expires on _____.

DANIEL KNIGHT, in his official capacity as
Prosecuting Attorney of Boone County

By: Charles J. Dykhouse

Title: County Counselor for Boone County

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Charles J. Dykhouse, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18th day of May, 2010.

Deborah A. Sprague
Notary Public

DEBORAH A. SPRAGUE
Notary Public - Notary Seal
State of Missouri
County of Boone
My Commission Expires August 10, 2012
Commission #08379046

My commission expires on August 10, 2012.

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ADDENDUM A

Work to Be Completed by Planned Parenthood of Kansas and Mid-Missouri at its Columbia Center as Described in Paragraph 6 of the Settlement Agreement

Corridors and Patient-Traveled Doors

In light of the Columbia Center's specific configuration, the Department determines that the facility's existing corridor width of 5 feet and door widths and construction are acceptable if combined with the following modifications. The door swing in the procedure and recovery rooms will be made so that they continue to swing into the room, but swing next to the wall and out of the way of the gurney. The fire extinguisher on the wall opposite the recovery room will be moved to the same side as the recovery room. The fire extinguisher adjacent to the procedure room will be moved to the same side as the procedure room. These modifications will provide extra maneuvering room for a stretcher into either room.

Construction Type/Sprinkler System

The Regulations require single story facilities to be Type II (111) construction. The facility will become fully equipped with a sprinkler system, which will be an acceptable alternative to the construction type. The design specifications for the sprinkler system must be submitted to the Department for approval before construction begins.

Dimensions for procedure room

The Regulations require the procedure room to be 12 feet length and width and a minimum ceiling height of 9 feet. The procedure room to be used by the Columbia Center is

12 feet by 9 feet, 1/2 inch, with a ceiling height of 8 feet, 6 inches. These dimensions are an acceptable alternative because the facility will only use one procedure room.

Personnel Change Rooms

The Regulations require personnel change rooms for each sex, be located convenient to the procedure room, and each equipped with a toilet and lavatory. The facility may have only one, unisex personnel change room because the facility will only use one procedure room.

Procedure Room Lighting

The Regulations require that the procedure room be equipped with a ceiling-mounted surgical light. The Department grants a deviation from this Regulation to the Columbia Facility provided that the procedure room be equipped with a wall-mounted surgical light and gooseneck light.

Patient Change Rooms

The Regulations require at least two patient change rooms with storage for personal effects. The facility shall be allowed to use only one patient change room and to have patient belongings travel with the patient in a secure container, if it uses only one procedure room and does not use the procedure room as the change room.

Counseling Room Dimensions

The Regulations require that counseling rooms shall be separate and not smaller than ten feet by ten feet (10' x 10'). The facility shall be allowed to use its counseling room that is eight feet by ten feet, eleven inches (8' x 10', 11'').

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Scrub Facility

The Regulations require knee or foot-operated scrub facilities located immediately outside the procedure room. The Facility shall be allowed to use a hands-free scrub sink located in the former procedure room which will no longer be used as a procedure room, and which is adjacent to the usable procedure room.

Sterilizing Room

The Facility shall provide a sterilization room with positive air pressure in relation to adjacent areas, in accord with 19 CSR 30-30.070(2)(v). The Facility shall also provide a separate soiled/decontamination room with a constant running exhaust.

Additional Items:

The following items shall also be completed:

The facility shall install five (5) additional exit signs to clearly indicate the direction of exit travel.

The facility shall make ceiling tile in the clinical area so that it is smooth and easily cleanable.

The patient toilet facility shall be equipped with a constant running exhaust.

All open cabinet storage of supplies in the procedure room must be converted into closed cabinets in accord with the Regulations.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.070(2) shall apply in full to the Columbia Center. DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the

requirements of 19 CSR 30-30.070(2) except as specifically set forth above, and agrees that it will not require changes not set forth in above unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to be no longer in compliance with those requirements.

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ADDENDUM B

Modifications of Brous Center requirements.

The Brous Center's quality assurance program will review all medication abortion complications, but will not be required to review the following items set forth in 19 CSR 30-30.060(3)(J) that are not applicable to medication abortion: cases that resulted in a stay of more than twelve (12) hours, and cases in which gestational age was determined to be beyond eighteen (18) weeks. The quality assurance program will not be required to review intraoperative and postoperative complications, however, complications of medication abortion, including incomplete or failed medication abortions that requires surgical completion, and hemorrhaging that requires surgical intervention following a medication abortion, shall be reviewed as part of the quality assurance program.

The Brous Center will not be required to provide medication abortion in a procedure room or a recovery room, and requirements that relate to the procedure and/or recovery room are therefore inapplicable. Continuous physician services or registered professional nursing services will be provided whenever an abortion patient is in the Brous Center, once the patient has received the mifepristone or other medication that begins the abortion process. PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060 (3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)(4). 19 CSR 30-30.060(3)(H)(2) and 19 CSR 30-

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30.060(4) (A) through (C) do not apply to the inducement of medication abortions at the Brous Center.

The Brous Center will provide Anti-Rh immune globulin therapy to Rh negative patients during the appointment where the patient receives the mifepristone or other medication that begins the abortion process. The Brous Center need not perform urinalysis or a pelvic exam for every abortion patient, because it performs ultrasound on every patient to confirm pregnancy and gestational age. It will also perform hematocrit or hemoglobin and RH typing on every abortion patient. The option to perform a hemoglobin test instead of a hematocrit shall apply to the Columbia Center as well as the Brous Center.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.050 and 19 CSR 30-30.060 shall apply in full to the Brous Center.

PELVIC EXAM PREREQUISITE TO HORMONAL CONTRACEPTIVES: UNJUSTIFIED INFRINGEMENT ON CONSTITUTIONAL RIGHTS, GOVERNMENTAL COERCION, AND BAD PUBLIC POLICY

HEATHER S. DIXON*

I. INTRODUCTION

Family planning programs receiving federal funds under Title X,[1] Medicaid,[2] and block grants[3] mandate pelvic exams as a condition to access to oral contraceptives and sometimes other hormonal methods of birth control.[4] Requiring a pelvic exam, an invasive procedure, infringes upon

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* J.D. Candidate, 2004, Case Western Reserve University School of Law; B.A., 1998, University of Pennsylvania. I would like to thank Professor Jonathan L. Entin for his supervision and feedback in writing this Article and Professor Melvyn R. Durchslag for introducing me to constitutional law.

[1] Title X family planning program of the Public Health Services Act, 42 U.S.C. §§ 300 to 300a-6a (2003). The provisions were enacted in 1970 (with program guidelines specified by regulations of the Department of Health and Human Services ("HHS") and 42 C.F.R. § 59 (2004) and administered by the Office of Population Affairs ("OPA")) to make contraceptive services available to all who need them but are unable to afford them without governmental assistance. The program was designed to fulfill President Nixon's promise that "no American woman . . . be denied access to family planning assistance because of her economic condition." H.R. DOC. NO. 91-139, at 8 (1969).

[2] Joint federal-state Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. § 1396 (2000). Under Medicaid, the federal government (through HHS) sets broad program parameters, including mandated provision of family planning services, and the individual states control the program's administration. Medicaid is the largest source of public funding for family planning services in the United States. Rachel Benson Gold, *Key Policies Emerging to Govern Delivery of Family Planning in Medicaid Managed Care*, THE GUTTMACHER REPORT ON PUBLIC POLICY, Feb. 1999, at 3, 3, *available at* http://www.guttmacher.org/journals/tgr_archive.html (last visited Feb. 1, 2004).

[3] Maternal and Child Health ("MCH") Block Grant program, Title V of the Social Security Act, 42 U.S.C. §§ 701–09 (2000), and Social Services block-grant program, Title XX of the Social Security Act, 42 U.S.C. § 1397 (2000).

[4] Discussion of contraception in this Article refers to reversible contraception and focuses primarily on oral contraception, though the arguments are likely to apply to other hormonal methods of contraception for which pelvic exams are suggested. Depo-Provera, the only injectable contraceptive currently available, is administered once every twelve weeks. Norplant, the only contraceptive implant currently available, is a set of five matchstick-sized strips that are inserted under the skin and slowly release hormones for a period of up to five years or until removed. While NuvaRing (an intravaginal, hormonal contraceptive device) and Ortha Nova (a transdermal, hormonal contraceptive patch) are too new to be mentioned in the literature about publicly funded contraception, the source and rationale of the pelvic exam requirement for oral contraceptives, *see infra* notes 275–277 and accompanying text, suggest that the federal funding guidelines will also require pelvic exams for access to these new products. Indeed, their package labeling states that it is

women's bodily privacy rights. Patients seeking hormonal forms of birth control from private providers are not subject to this absolute requirement.[5] Nor are men seeking contraception or sexual performance–enhancing drugs from publicly funded clinics required to undergo invasive prostate exams, despite presenting the same opportunity for preventive health care as women seeking oral contraceptives. The pelvic exam requirement increases the cost of providing oral contraceptives, results in decreased utilization of other publicly funded health care services, and imposes unnecessary discomfort and anxiety. These consequences deter impoverished women, particularly adolescents, from seeking such highly effective forms of contraception.

This Article argues that the risks posed to individuals and society by the pelvic exam requirement far outweigh the drug-related risks posed to any woman who makes a voluntary, informed decision to accept them. Following an overview of publicly funded contraception in Part II, the Article focuses on the unconstitutionality of the pelvic exam requirement. Part III examines its violation of substantive due process rights to contraceptive access, reproductive autonomy, and bodily integrity due to its lack of any rational basis. Part IV discusses the requirement's impact on the equal protection rights of women and minorities. Part V argues that the requirement is an unconstitutional condition on the exercise of fundamental reproductive privacy rights. Part VI focuses on mandated pelvic exams as an impermissible agency interpretation of statutory instructions.

In Part VII this Article argues that sound public policy compels the elimination of the unnecessary barrier to contraception that a mandatory pelvic exam creates. The requirement deters women from obtaining effective contraceptives, resulting in unwanted pregnancies and abortions as well as increased costs to individuals and society. The pelvic exam requirement perpetuates gender stereotypes by decreasing women's actual and perceived autonomy: unwanted pregnancies potentially derail education and career goals and force maternal roles and responsibilities upon women who do not desire them. Further, the requirement is inconsistent with other laws concerning medical decisions and Title X programs.

The Article concludes with a proposal to allow women to obtain oral contraceptive prescriptions by signing an informed consent and release after having been offered a pelvic exam and advised of the risks of foregoing it. Allowing women who use federally funded clinics the option to exercise their fundamental right to reproductive autonomy without requiring the forfeiture of bodily privacy rights will decrease individual and

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"good medical practice" for women using these products to have physical evaluations that include "special reference to . . . pelvic organs and vagina (including cervical cytology)." NuvaRing package insert labeling, *infra* note 277.

[5] Private providers who do not receive Title X funds (including all physicians operating for profit) may use discretion in administering pelvic exams.

social burdens imposed by unwanted pregnancies and abortions, increase women's autonomy, and help erode gender role stereotypes.

II. Overview of Publicly Funded Contraception

A. The Importance of Contraception Provided by Publicly Funded Family Planning Programs

There are 3117 U.S. agencies that provide publicly funded contraceptive services[6] to over 7000 family planning clinics nationwide.[7] The average woman, who wants only two children, will use contraceptives for twenty to thirty years of her life.[8] Thirty-three million U.S. women are in need of contraceptive services at any given time, and more than sixteen million of these women need these services subsidized.[9] Of the 6.5 million women actually receiving subsidized family planning services, two-thirds do so at clinics supported by Title X funds.[10] While most women prefer to see private physicians, low-income women are often forced to utilize publicly funded family planning clinics instead.[11]

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[6] Lawrence B. Finer et al., *U.S. Agencies Providing Publicly Funded Contraceptive Services in 1999*, 34 Persp. on Sexual and Reprod. Health 15, 17 (2002).

[7] Cynthia Dailard, *Challenges Facing Family Planning Clinics and Title X*, The Guttmacher Report on Public Policy, Apr. 2001, at 8, 8, *available at* http://www.guttmacher.org/journals/tgr_archive.html (last visited Feb. 1, 2004).

[8] Alan Guttmacher Inst., Fulfilling the Promise: Public Policy and U.S. Family Planning Clinics 10 (2000) [hereinafter Alan Guttmacher Inst., Fulfilling the Promise], *available at* http://www.guttmacher.org/pubs/fulfill.pdf (last visited Feb. 1, 2004); Alan Guttmacher Inst., *Facts in Brief: Contraceptive Use* (2004) [hereinafter Alan Guttmacher Inst., *Facts in Brief*], http://www.guttmacher.org/pubs/fb_contr_use. html (last visited Feb. 1, 2004).

[9] Alan Guttmacher Inst., *Contraceptive Need and Services* tbl. 1 (1995), http://www.guttmacher.org/pubs/contra_tables.html (last visited Feb. 1, 2004).

[10] Dailard, *supra* note 7, at 8; *see also* Jennifer J. Frost, *Public or Private Providers? U.S. Women's Use of Reproductive Health Services*, Fam. Plan. Persp., Jan.-Feb. 2001, at 4, 4. This Article will focus largely on Title X because its provision of funds to a majority of public family planning clinics, in conjunction with the mandate that clinics receiving its funds follow Title X standards in treating all of their patients (regardless of the clinics' receipt of other types of public funds), has resulted in Title X essentially setting the standards for all publicly funded family planning services in the United States. Rachel Benson Gold, *Title X: Three Decades of Accomplishment*, The Guttmacher Report on Public Policy, Feb. 2001, at 5, 6, *available at* http://www.guttmacher.org/journals/tgr_archive.html (last visited Feb. 1, 2004); Alan Guttmacher Inst., Fulfilling the Promise, *supra* note 8, at 14, *available at* http://www.guttmacher.org/pubs/fulfill.pdf. Also, Title X is the only federal program with the sole purpose of providing family planning services. *Id.* at 12.

[11] Although Medicaid theoretically allows patients to choose either public or private family planning providers, Medicaid patients have difficulty finding private physicians who will serve them. In one survey, forty-six percent of obstetrician-gynecologists did not serve Medicaid patients, and those who did typically saw very few. *See* David J. Landry & Jacqueline Darroch Forrest, *Private Physicians' Provision of Contraceptive Services*, Fam. Plan. Persp., Sept.-Oct. 1996, at 203, 203. Seventy-one percent of women who made a medical family planning visit paid for by Medicaid received care at a public clinic, despite most low-income women's preference for a private provider. *Id.*

More than three million unplanned pregnancies occur in the United States each year, forty-seven percent of which result from the seven percent of women who do not use contraception.[12] Each year, publicly funded contraceptive services help prevent 1.3 million unplanned pregnancies, which otherwise would result in 632,300 abortions, 533,800 unintended births, and 165,000 miscarriages.[13] Title X alone helps American women avoid one million unintended pregnancies each year.[14] Every tax dollar spent for contraceptive services saves three dollars in Medicaid costs for health care for pregnant women and newborns.[15]

B. The Importance of Oral Contraceptives and Other Hormonal Contraceptive Methods

More than eighteen million American women use oral contraceptives, making "the pill" the most frequently used form of reversible contraception in the United States.[16] It is also one of the safest drugs currently marketed.[17] Hormonal contraceptives are by far the most effective method of reversible contraception,[18] with a failure rate of less than one percent for Norplant, Depo-Provera, and oral contraceptives when used in perfect compliance (and only a five percent failure rate for oral contraceptives in actual observed use).[19] Condoms, which are the second most popular and second most effective form of reversible contraception, have a twelve to sixteen

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[12] Alan Guttmacher Inst., *Facts in Brief*, *supra* note 8, http://www.guttmacher.org/pubs/fb_contr_use.html.

[13] Jacqueline Darroch Forrest & Renee Samara, *Impact of Publicly Funded Contraceptive Services on Unintended Pregnancies and Implications for Medicaid Expenditures*, FAM. PLAN. PERSP., Sept.-Oct. 1996, at 188, 193 tbl. 4.

[14] Dailard, *supra* note 7, at 8.

[15] Forrest & Samara, *supra* note 13, at 193. Prevention of unplanned pregnancies with public services keeps 841,800 qualified women from needing pregnancy-related Medicaid assistance each year. *Id.*

[16] Michael J. Rosenberg et al., *Compliance, Counseling and Satisfaction with Oral Contraceptives: A Prospective Evaluation*, FAM. PLAN. PERSP., Mar.-Apr. 1998, at 89, 89 (citing Michael J. Rosenberg et al., *Unintended Pregnancies and Use, Misuse and Discontinuation of Oral Contraceptives*, 40 J. REPROD. MED. 355 (1995)).

[17] Rosenberg et al., *supra* note 16, at 89 (citing Philip C. Hannaford, *Combined Oral Contraceptives: Do We Know All of Their Effects?*, 51 CONTRACEPTION 325 (1995); CONTRACEPTIVE TECHNOLOGY 405, 409 (Robert A. Hatcher et al. eds., 16th rev. ed. 1994)).

[18] Failure rates for nonhormonal contraceptive methods are: male condom, 12%; diaphragm, 18%; withdrawal, 19%; periodic abstinence, 20%; female condom, 21%; spermicides, 21%; sponge, 30%; cervical cap, 30%; no method, 85%. James Trussell et al., *The Economic Value of Contraception: A Comparison of 15 Methods*, 85 AM. J. PUB. HEALTH 494, 495 (1995). While some forms of intrauterine devices (IUDs) have lower failure rates, not all forms are nonhormonal. BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, THE NEW OUR BODIES, OURSELVES: A BOOK BY AND FOR WOMEN 264 (1992) (citing a 0.42% failure rate in the copper-T IUD, 3.0% failure rate for IUDs as a class). Insertion of the device requires placement by a clinician in a procedure as invasive as a pelvic exam, and contraindications preclude its use for most teenagers. Am. Acad. of Pediatrics, Comm. on Adolescence, *Contraception and Adolescents*, 86 PEDIATRICS 134 (1990).

[19] SmarterSex.Org, *Contraceptives: How Effective Are They?*, *at* http://www.smartersex.org/contraception/efficacy_chart.asp (last visited Feb. 1, 2004).

percent failure rate, causing a significant risk of unintended pregnancy.[20] Hormonal contraceptives are also considered more convenient than other forms of birth control.[21] Because hormonal methods of birth control are independent of intercourse, they are "largely outside the control and even the knowledge of a woman's male partner . . . ."[22] Therefore, such methods are essential in providing women reliable control over their fertility.

III. Substantive Due Process Violations

Fifth Amendment substantive due process principles prohibit a federal regulation from infringing unjustifiably upon a constitutional right.[23] When the infringed right has been deemed fundamental by the U.S. Supreme Court, the regulation is subject to strict scrutiny review.[24] The first section of this Part discusses the pelvic exam requirement's infringement upon implied fundamental rights. The second section explains the requirement's violation of women's substantive due process rights, which is unjustified under strict scrutiny review.[25] The final section illustrates how the requirement remains impermissible under both intermediate level and rational basis standards of review.

A. The Requirement Infringes upon Implied Fundamental Rights of Privacy

Many constitutional privacy rights that are not explicitly articulated in the Constitution are deemed to exist by implication.[26] The pelvic exam requirement infringes upon the implied fundamental privacy rights to use contraceptives and control reproduction as well as to maintain bodily integrity.[27]

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[20] Trussell et al., *supra* note 18, at 495 (citing a twelve percent failure rate for condoms); Lisa A. Hayden, *Gender Discrimination Within the Reproductive Health Care System: Viagra v. Birth Control*, 13 J.L. & Health 171, 180 (1999) (citing a sixteen percent failure rate for condoms).

[21] *See, e.g.*, Howard W. Ory et al., Making Choices: Evaluating the Health Risks and Benefits of Birth Control Methods 5–9 (1983).

[22] Jacqueline E. Darroch, *The Pill and Men's Involvement in Contraception*, Fam. Plan. Persp., Mar.-Apr. 2000, at 90, 90.

[23] State regulations mandating pelvic exams are equally prohibited from infringing upon constitutional rights by the Fourteenth Amendment's Due Process Clause.

[24] United States v. Carolene Prods. Co., 304 U.S. 144, 153 n.4 (1938); *see also* Carey v. Population Servs. Int'l, 431 U.S. 678 (1977) (holding that strict scrutiny must be met for the government to justify a law restricting access to contraceptives).

[25] While the pelvic exam requirement is a condition on federal spending rather than on all women seeking hormonal contraception, discussion of a general rule's compliance with due process requirements serves as a preface to an examination of the prerequisite's constitutionality as a condition on spending. *See infra* Part V.

[26] *See* Roe v. Wade, 410 U.S. 113 (1973); Griswold v. Connecticut, 381 U.S. 479 (1965); Erwin Chemerinsky, Constitutional Law: Principles and Policies 762 (2d ed. 2002).

[27] The requirement also arguably infringes upon implied medical care decisionmaking rights. *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), and *Wash-*

1. Right To Use Contraceptives and Control Reproduction via Access to Contraceptives

In 1965, the Supreme Court acknowledged the existence of a fundamental constitutional right for married people to purchase and use contraception.[28] In 1972, the Court extended this right to unmarried individuals, expanding it from one of marital privacy to one of reproductive privacy.[29] The result was a fundamental right of access to contraceptives, free from unjustified governmental interference, in order to control reproduction.[30] The Court famously held that "[i]f the right of privacy means anything, it is the right of the *individual* . . . to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[31]

Despite the fact that the pelvic exam prerequisite does not bar access to all forms of birth control, it is impermissible under *Griswold v. Connecticut* and *Eisenstadt v. Baird* because they hold that there is a right of access to *effective* contraception.[32] By today's standards, nonhormonal methods' twelve percent or greater failure rates[33] constitute far less than the required efficacy.[34] The cases emphasize the right to determine family size—

ington v. Harper, 494 U.S. 210 (1990), established the existence of a medical care decisionmaking right, which includes the right to refuse life-saving treatment. Therefore, even if the pelvic exam had the effect of saving a woman's life, she has the right to refuse it.

[28] Griswold v. Connecticut, 381 U.S. 479 (1965).

[29] Eisenstadt v. Baird, 405 U.S. 438 (1972).

[30] *See id.* at 453; *see also* Planned Parenthood v. Casey, 505 U.S. 833, 851–53 (1992) (affirming the right's continued existence).

[31] *Eisenstadt*, 405 U.S. at 453.

[32] For single or married people to control the number and spacing of their children, the contraception to which they are entitled access must be effective. Thus, taken together, *Eisenstadt* and *Griswold* create a right of access to effective contraception for all. *See* Planned Parenthood Fed'n v. Schweiker, 559 F. Supp. 658, 660, 666 (D.D.C. 1983) (considering the lack of efficacy of nonprescription birth control as a factor in finding a parental notice restriction on adolescents' access to hormonal birth control unjustifiable because it would undermine Title X clinics' ability to reduce the number of unintended births and pregnancies).

[33] *See supra* note 18. While sterilization is a virtually one hundred percent effective nonhormonal method of contraception, it is equally or more invasive than a pelvic exam and would also preclude exercise of the right to determine number and spacing of children for women who desire to have more children in the future. Similarly, while some forms of IUDs are nonhormonal and provide levels of efficacy comparable to that of oral contraceptives, they require an insertion procedure as invasive as a pelvic exam, *see supra* note 18, work via a mechanism of action that is not fully understood and thus may implicate religious or moral concerns, *see infra* note 241 and accompanying text, and are associated with risks that many consider greater than those associated with oral contraceptives. *See* David Hubacher, *The Checkered History and Bright Future of Intrauterine Contraception in the United States*, 34 PERSP. ON SEXUAL & REPROD. HEALTH 98, 98–99 (2002); Rod Seeley et al., *Control of Reproduction*, http://www.mhhe.com/biosci/ap/seeleyap/repro/reading8.mhtml (2001) (last visited Feb. 1, 2004).

[34] Compare the products liability principle of an "unavoidably unsafe" product, under which courts have held that an oral contraceptives manufacturer can only be held liable for harm resulting from its product's use if, at that time, there existed an alternative product that was at least as effective and provided less risk. A mere "alleged modicum of reduction

a right hardly fulfilled by a failure rate that would leave the average woman with four more pregnancies than desired if she used the most effective nonhormonal contraception for the thirty years the typical American woman spends trying to avoid pregnancy.[35] Therefore, denying a woman access to hormonal methods of contraception amounts to a ban on effective contraception and is impermissible under *Griswold* and *Eisenstadt*.

Even if the pelvic exam requirement does not *prevent* access to effective contraception, regulations *restricting* access to contraceptives are impermissible under the Supreme Court's holding in *Carey v. Population Services International*.[36] *Carey* made clear the sacrosanct status of the right to effective contraception by holding that strict scrutiny must be met for the government to justify a law restricting access to contraceptives.[37] In *Carey*, the Court declared unconstitutional a law that made it criminal to advertise or display contraceptives, to distribute or sell contraceptives to persons under sixteen, or for anyone besides a licensed pharmacist to distribute contraceptives to persons over fifteen.[38] The Court found that limiting distribution of contraceptives to pharmacists unduly restricted access to birth control (unjustifiably infringing the right to control procreation) and that the law violated the rights of those under sixteen to have access to contraceptives.[39]

2. Right to Bodily Integrity

The Supreme Court has held that the individual has a dignity interest in bodily integrity.[40] This principle is "deeply embedded in our . . . constitutional traditions."[41] The prominence of the fundamental right to bodily integrity within the context of substantive due process privacy rights is highlighted by *Roe v. Wade*[42] and *Planned Parenthood v. Casey*,[43] both of which discuss the importance of a woman's right to bodily integrity in relation to the government's interests in protecting life and health. A pel-

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of risk" does not justify a loss of effectiveness. Joanne Rhoton Galbreath, Annotation, *Products Liability: What Is an "Unavoidably Unsafe" Product?*, 70 A.L.R. 4th 16, §§ 4–5 (1989) (citing Ackley v. Wyeth Laboratories, Inc., 919 F.2d 397 (6th Cir. 1990); White v. Wyeth Labs., Inc., 533 N.E.2d 748 (Ohio 1988); Patten v. Lederle Labs, 676 F. Supp. 233 (D. Utah 1987)).

[35] ALAN GUTTMACHER INST., FULFILLING THE PROMISE, *supra* note 8, at 10, *available at* http://www.guttmacher.org/pubs/fulfill.pdf.

[36] 431 U.S. 678 (1977).

[37] *Id.* at 685–86.

[38] *Id.* at 682.

[39] *Id.* at 686.

[40] *See, e.g.*, Winston v. Lee, 470 U.S. 753, 761 (1985) (holding that compelling a criminal defendant to submit to surgery in order to retrieve a bullet necessary for the state's prosecution would violate the defendant's personal privacy and bodily integrity).

[41] Dawn Johnsen, *From Driving to Drugs: Governmental Regulation of Pregnant Women's Lives After* Webster, 138 U. PA. L. REV. 179, 201 (1989).

[42] 410 U.S. 113 (1973).

[43] 505 U.S. 833 (1992).

vic exam encroaches upon this fundamental right to bodily integrity. Such infringement is unconstitutional unless sufficiently justified by a governmental interest. Although the amount of justification necessary is determined by the level of scrutiny under which it is reviewed, the requirement fails under each level of review.

B. The Pelvic Exam Requirement Is Unconstitutional Under the Due Process Clause of the Fifth Amendment

The Supreme Court has held that strict scrutiny must be met for the government to justify a law restricting access to contraceptives.[44] To survive strict scrutiny review, the pelvic exam requirement must be narrowly tailored to serve a compelling governmental interest.[45] Although it has been established that the government has a compelling interest in protecting women's health,[46] the requirement fails strict scrutiny review because it is not narrowly tailored to the goal of protecting women's health from the preventable adverse effects of oral contraceptive use: the pelvic exam does not serve its stated purpose, it is not necessary, and it is overly broad. The requirement constitutes a burden that sufficiently outweighs any governmental interest under strict scrutiny review.

1. The Requirement Does Not Serve Its Stated Purpose

The purpose of the pelvic exam requirement is to protect women's health.[47] More specifically, its goal is to identify women who are at an unacceptably high risk of experiencing harmful side effects of hormonal contraceptives and preclude them from receiving prescriptions.[48] The pelvic exam requirement fails strict scrutiny review because it does not serve this purpose. Risk of cervical cancer is the only potential danger of oral contraceptive use that the pelvic exam can reveal.[49] Mandatory pelvic

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[44] *See supra* note 24.

[45] *See, e.g.*, Adarand Constructors v. Pena, 515 U.S. 200 (1995); Sugarman v. Dougall, 413 U.S. 634 (1973).

[46] *Roe*, 410 U.S. at 162 (finding that "the state does have an important and legitimate interest in preserving and protecting the health of the pregnant woman"); *Casey*, 505 U.S. 833, 875–76 (citing *Roe*, 410 U.S. at 162).

[47] *See infra* note 281; *see also infra* notes 275–277 and accompanying text.

[48] The purpose of Food and Drug Administration (FDA) labeling information that is used on hormonal contraceptive packaging, *see infra* notes 276–277 and accompanying text, is "to promote the safe and effective use of prescription drug products by patients and to ensure that patients have the opportunity to be informed of the benefits and risks involved in the use of prescription drug products." 45 Fed. Reg. 60,754, 60,754 (Sept. 12, 1980).

[49] *See* Felicia H. Stewart et al., *Clinical Breast and Pelvic Examination Requirement for Hormonal Contraception: Current Practice vs. Evidence*, 285 JAMA 2232, 2234 tbl. 2 (2001) (listing factors that render hormonal contraceptive methods "not recommended," as requiring "caution or special monitoring," or for which use has "disadvantages," of which the only ones detectable upon pelvic exam are existing cervical cancer or precursors to cervical cancer (cervical intraepithelial neoplasia), pregnancy (for which contraceptive use

exams do not serve their purpose of protecting women's health for at least three reasons: it has not been proven that oral contraceptive use is causally connected with cervical cancer, the exam is inadequate in accurately detecting the risks it is designed to identify, and the requirement actually *increases* risks to women's health.

a. There Is No Proven Causal Connection Between Hormonal Contraception and the Risks the Exam Requirement Is Designed To Detect

Under strict scrutiny review, a legislative rationale based on a mere associative correlation is insufficient justification for restricting a constitutional right. Rather, a causal connection between the relevant factors must be demonstrated in order to show that the requirement is necessary to achieve the government's compelling purpose.[50] Therefore, if oral contraceptives are merely *associated with*, but do not *cause*, cervical cancer or acceleration of cervical cancer, an exam to detect risk factors for cervical cancer cannot be *necessary* to protect women's health.

Public family planning clinics initially required annual pelvic exams for women receiving oral contraceptives in order to detect genital cancer, to which oral contraceptive use was suspected, though not shown, to have a causal connection.[51] It has since been demonstrated that not only do oral contraceptives not cause endometrial or ovarian cancer, the drugs may actu-

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is contraindicated not because of health risks to the mother or fetus but because it will not be efficacious), and unexplained vaginal bleeding (which is clearly detectable without a pelvic exam)); Mary-Ann B. Shafer, *Annual Pelvic Examination in the Sexually Active Adolescent Female: What Are We Doing and Why Are We Doing It?*, 23 J. ADOLESCENT HEALTH 68, 71 (1998) (listing risk factors for developing cervical cancer, of which the only two detectable upon pelvic exam are human papillomavirus ("HPV") and precancerous lesions). Women who have or are at risk for cervical cancer are often advised not to use oral contraceptives because there is some suggestion that the drugs' use may precipitate cervical cancer development or growth in those at risk. Victor Moreno et al., *Effect of Oral Contraceptives on Risk of Cervical Cancer in Women With Human Papillomavirus Infection: The IARC Multicentric Case-Control Study*, 359 LANCET 1085 (2002) (concluding that long-term use of oral contraceptives *could* be a co-factor that increases risk of cervical cancer by up to fourfold in women who test positive for cervical HPV DNA); Fabio Parazzini et al., *Time Since Last Use of Oral Contraceptives and Risk of Invasive Cervical Cancer*, 34 EUR. J. CANCER 884, 887–88 (1998) (positing that oral contraceptive use should be "critically reconsidered for women with a diagnosis of cervical intraepithelial neoplasia," concluding that there is an excess risk of cervical cancer for long-term users of oral contraceptives with neoplasia); JAMES OWEN DRIFE, THE BENEFITS AND RISKS OF ORAL CONTRACEPTIVES TODAY 22 (2d ed. 1996) (citing Giske Ursin et al., *Oral Contraceptive Use and Adenocarcinoma of the Cervix*, 344 LANCET 1390 (1994)).

[50] *See* CHEMERINSKY, *supra* note 26, at 762 (noting that a law will be upheld under strict scrutiny only if it is necessary to achieve a compelling governmental purpose).

[51] ABRIDGED PROCEEDINGS OF THE SECOND CONFERENCE ON PUBLIC FAMILY PLANNING CLINICS: HOW TO ORGANIZE/HOW TO OPERATE 49 (G.D. Searle & Co. Reference and Resource Program ed. 1966) [hereinafter HOW TO ORGANIZE] (acknowledging the lack of evidence of a causal connection between oral contraceptive use and genital cancer, but arguing pelvic exams should be performed nonetheless).

ally *protect against* these cancers.[52] While some researchers today still suspect that there is a causal link between oral contraceptive use and cervical cancer, no sound scientific data supports this hypothesis,[53] and data suggests otherwise.[54]

b. The Exam Does Not Accurately Detect the Risks It Is Designed To Identify

Even if oral contraceptive use is linked to the development of cervical cancer, a pelvic exam (which includes a pap smear) does not serve its purpose because it does not accurately identify women with precancerous lesions or human papillomavirus ("HPV") that will lead to cancer. Results of a pap smear, the best screening tool available to detect precancerous lesions, may be falsely negative in fifteen to thirty percent of women with the lesions, even when obtained and interpreted correctly.[55] Of those lesions detected that are low-grade, fifty to seventy percent will spontaneously regress or remain stable for many years rather than develop into cancer.[56] While HPV can be detected by a pelvic exam, of the millions of women infected with it, only a few will ever develop cervical cancer.[57] Therefore, the exam does not accurately predict who is most likely to develop cervical cancer. Most importantly, even if the exam detects the existence of or precursors to cervical cancer, physicians maintain that "cervical intraepithelial neoplasia and cervical cancer awaiting treatment are not conditions that require avoiding hormonal methods [of contraception] or for which caution is recommended."[58]

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[52] Family Health Int'l, *What Are the Benefits and Risks of Combined Oral Contraceptives?*, *at* http://www.fhi.org/en/RH/Pubs/factsheets/OCriskben.htm (2003) (last visited Feb. 1, 2004); David T. Baird & Anna F. Glasier, *Hormonal Contraception*, 328 NEW ENG. J. MED. 1543 (1993); DRIFE, *supra* note 49, at 34 (noting the continued "standard" advice that women using oral contraceptives have regular pelvic exams despite recent research concluding oral contraceptives are not linked to cervical cancer). Furthermore, pelvic examination has not been found effective as a screening measure to reduce ovarian cancer mortality and is not recommended for that purpose. Stewart et al., *supra* note 49, at 2238 (citing, inter alia, Sonia Regina Grover & Michael Quinn, *Is There Any Value In Bimanual Pelvic Examination As a Screening Test?*, 162 MED. J. AUSTL. 408 (1995)).

[53] LARA V. MARKS, SEXUAL CHEMISTRY: A HISTORY OF THE CONTRACEPTIVE PILL 181 (2001) (stating that "[n]o conclusive evidence has been collected anywhere to date on the connections between the pill and cervical cancer"); Stewart et al., *supra* note 49, at 2237–38 (referring to the risk of cervical cancer development or precursor progression as a "theoretical" concern); Hannaford, *supra* note 17, at 325 (stating that "[u]ncertainty also remains concerning the association between pill use and risk of carcinoma of the cervix").

[54] *E.g.*, DRIFE, *supra* note 49, at 34 (citing Baird & Glasier, *supra* note 52, for the proposition that there appears to be no increase in the risk of cervical cancer among women who take combined oral contraceptives).

[55] AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES FOR WOMEN'S HEALTH CARE 151 (1996) [hereinafter AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES].

[55] *Id.*

[57] *Id.* at 137.

[58] Stewart et al., *supra* note 49, at 2237.

c. Mandatory Pelvic Exams Will Result in an Increased Risk to Women's Health

The pelvic exam requirement will necessarily result in greater risks to women's health for three reasons. First, there will be an increase in pregnancies among women denied oral contraceptives (whether due to unsuitability for the drug or refusal to submit to the pelvic exam) because all other birth control methods except abstinence are less effective.[59] Carrying a pregnancy to term poses a greater risk to women's health than do oral contraceptives.[60] Having an abortion also carries much higher risks than do oral contraceptives.[61] Therefore, women who are forced to use a less effective method of birth control face risks of pregnancy and abortion that could be avoided with hormonal contraception and that exceed the risks of oral contraceptive use, even without a pelvic exam.

Second, women's avoidance of pelvic exams will result in a decrease in use of the other general health[62] and sexual health services, such as screening for sexually transmitted diseases, that are provided by publicly funded clinics.[63] Women who opt to use over-the-counter contraception, or none at all, in order to avoid mandatory pelvic exams will not receive the additional health services that are provided at a clinic visit for a hormonal contraceptive prescription.[64]

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[59] *Id.* at 2232 (stating that pelvic examinations "may reduce access to highly effective contraceptive methods, and may therefore increase women's overall health risks"); *see supra* notes 18–19 and accompanying text.

[60] Family Health Int'l, *A Comparison of Annual Deaths from Oral Contraceptive Related Diseases for Four Regions* (providing data that, for every 100,000 women in the western world, only six women using oral contraceptives die per year due to cervical cancer, while ten women *not* using oral contraceptives die from pregnancy), *at* http://www.fhi.org/en/RH/Pubs/factsheets/res_ BenandRisks.htm (2003) (last visited Feb. 1, 2004). This is particularly true for teenagers. Jessica R. Arons, Note, *Misconceived Laws: The Irrationality of Parental Involvement Requirements for Contraception*, 41 WM. & MARY L. REV. 1093, 1125 n.211 (2000) (citing Am. Acad. of Pediatrics, Comm. on Adolescence, *supra* note 18, at 136). Furthermore, the health risks of pregnancy and childbirth increase greatly when the pregnancy is unwanted. Sylvia A. Law, *Rethinking Sex and the Constitution*, 132 U. PA. L. REV. 955, 1017 n.220 (1984) (citing William Cates, Jr., *Legal Abortion: The Public Health Record*, 215 SCI. 1586, 1587 (1982)).

[61] THE MERCK MANUAL OF MEDICAL INFORMATION § 22, at ch. 255 (Mark H. Beers et al. eds., Second Home ed. 2003) [hereinafter MERCK MANUAL], *available at* http://www.merck.com/mrkshared/mmanual_home2/sec22/ch255/ch255c.jsp (last visited Feb. 1, 2004).

[62] For many economically disadvantaged women, entry into the public health care system (which provides general health care services) often occurs only upon a pregnancy scare or a decision to seek reproductive or other sexual health care services. Stewart et al., *supra* note 49, at 2236; *see also* 136 CONG. REC. S13,680 (daily ed. Sept. 25, 1990) (statement of Sen. Packwood) (acknowledging that for many low-income women, a Title X funded clinic is their only point of contact with the health care system).

[63] 136 CONG. REC. S13,676 (daily ed. Sept. 25, 1990) (statement of Sen. Kennedy) (noting that publicly funded family planning programs serve as the entry point into the health care system for many patients in need of other important sexual health services, including HIV testing).

[64] *See* Stewart et al., *supra* note 49, at 2232, 2236, 2238 (commenting on the missed opportunity for counseling on prevention of sexually transmitted diseases and preventative

Third, it is well accepted by physicians and public health officials that, for the vast majority of women, the benefits of oral contraceptive use far outweigh the risks.[65] Women on the pill experience approximately half the incidence of ovarian and endometrial cancer as do nonusers.[66] Oral contraceptive use is also associated with decreased risks of ovarian cysts, uterine fibroids, benign breast disease, and pelvic inflammatory disease.[67] Pill use has the benefit of drastically reducing unwanted pregnancies, particularly ectopic pregnancies.[68] The only women for whom benefits of hormonal contraception do not generally outweigh the risks are those who are over thirty-five years of age and smoke[69] and those for whom there is an absolute contraindication for pill use.[70] None of these factors requires a pelvic exam to detect.[71] Therefore, the research suggests that for most women oral contraceptives will *benefit* women's health, despite

services because of anxieties about the pelvic exam).

[65] *See* Family Health Int'l, *supra* note 52 (stating that although there are risks associated with oral contraceptive use, the risks tend to be small and are balanced by health benefits), *at* http://www.fhi.org/en/RH/Pubs/factsheets/ OCriskben.htm; DRIFE, *supra* note 49, at 41 (asserting that the benefits of oral contraceptive use greatly outweigh the risks); Hannaford, *supra* note 17, at 325–26. This is also particularly true for young women. Stewart et al., *supra* note 49, at 2237; DRIFE, *supra* note 49, at 35; Arons, *supra* note 60, at 1125 n.211 (citing Am. Acad. of Pediatrics, Comm. on Adolescence, *supra* note 18, at 136).

[66] DRIFE, *supra* note 49, at 23–26; Family Health Int'l, *supra* note 52, *at* http://www.fhi.org/en/RH/Pubs/factsheets/OCriskben.htm.

[67] HOLLY MEAD, INST. FOR WOMEN'S POL'Y RES., EVALUATING AN RX-TO-OTC SWITCH OF ORAL CONTRACEPTIVES: A COST-BENEFIT ANALYSIS 8 (2000) (citing Trussell et al., *supra* note 18, at 494); Diane B. Petitti, *Safety of Birth Control Pills*, *in* HENRY J. KAISER FAMILY FOUND., THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER 77, 77–115 (Sarah E. Samuels & Mark D. Smith eds., 1994); DRIFE, *supra* note 49, at 23.

[68] An ectopic pregnancy occurs when an embryo improperly implants in the fallopian tube (rather than the uterus), which poses great risks to the woman's life. Compared to women who use no form of birth control, women on the pill who become pregnant experience ninety percent fewer ectopic pregnancies. DRIFE, *supra* note 49, at 23 (citing David A. Grimes, *Reversible Contraception for the 1980s*, 255 JAMA 69 (1986)).

[69] DRIFE, *supra* note 49, at 39. Some, though not all, physicians consider smoking after age thirty-five an absolute contraindication to pill use. RICHARD P. DICKEY, MANAGING CONTRACEPTIVE PILL PATIENTS 200 (9th ed. 1998). The American College of Obstetricians and Gynecologists ("ACOG"), however, supports prescribing oral contraceptives to women over thirty-five who smoke if they are free of additional absolute contraindications to use and have been warned about the risks of use. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES, *supra* note 55, at 93.

[70] Stewart et al., *supra* note 49, at 2236. Absolute contraindications to oral contraceptive use include: breast cancer, hypertension, certain heart and liver diseases, diabetes mellitus, history of thromboembolic disease, stroke, some types of migraine headaches, breastfeeding within six weeks of giving birth, and pregnancy.

[71] *Id.* While a pelvic exam can detect pregnancy, it is not necessary because after fourteen days pregnancy would be suspected based on a medical history including missed period. *Id.* Pregnancy can also be detected by non- or less-invasive urine or blood screens. Moreover, there is no evidence that hormonal contraceptives are harmful for either the woman or the fetus if inadvertent exposure occurs during early pregnancy. Pregnancy is considered a contraindication because it renders the pill superfluous, not because it poses any known safety risks. *Id.*

any associated risks.[72] Consequently, deterring use of these drugs because of a mandated prior pelvic exam results in higher risks to women's health.

2. The Requirement Is Unnecessary

The pelvic exam requirement fails strict scrutiny review because the exam is not necessary to determine whether a hormonal contraceptive should be prescribed for a woman.[73] International medical guidelines support the safety of providing hormonal contraception without a pelvic exam.[74] European physicians deem pelvic exams irrelevant and unnecessary barriers to contraception accessibility.[75] Even within the United States, many physicians do not favor the required pelvic exam.[76] The FDA,[77] Planned Parenthood,[78] other family planning clinics, and many states allow women to defer the pelvic exam for up to three months after beginning hormonal contraception.[79] The Title X regulations allow a de-

[72] The World Health Organization has explicitly stated that "for young non-smoking women, the health benefits of oral contraceptive use (including an [sic] reduced risk of endometrial and ovarian cancers) far exceed the health risks." Emma Wilkinson, *HPV and Oral Contraceptives Linked to Cervical Cancer Risk*, 3 LANCET ONCOLOGY 265, 265 (2002).

[73] Stewart et al., *supra* note 49, at 2238 (concluding that "[h]ormonal contraception can safely be provided on the basis of careful medical history and blood pressure measurement. Breast and pelvic examinations and screening for cervical cancer and [sexually transmitted infections] . . . are not necessary for identifying women who should avoid these methods or need further evaluation before a decision about hormone use is reached."); *see also* Kim Best, *Medical Barriers Often Unnecessary*, NETWORK, FAMILY HEALTH INTERNATIONAL QUARTERLY BULLETIN, Vol. 21, No. 3 (2002) (stating that pelvic exams are only necessary before the insertion of IUDs and are not routinely needed for the safe use of hormonal methods of contraception), *available at* http://www.reproline.jhu.edu/English/6read/6issues/6network/v21-3/nt2131.htm (last visited Feb. 1, 2004).

[74] Cynthia Harper et al., *Provision of Hormonal Contraceptives Without a Mandatory Pelvic Examination: The First Stop Demonstration Project*, FAM. PLAN. PERSP., Jan.-Feb. 2001, at 13, 13; Stewart et al., *supra* note 49, at 2233 (citing the recommendation of both the World Health Organization and the U.S. Agency for International Development that "[a] pelvic examination is not necessary for safe use of combined oral contraceptives as a contraceptive method").

[75] Barbara A. Cromer & Maureen McCarthy, *Family Planning Services in Adolescent Pregnancy Prevention: The Views of Key Informants in Four Countries*, FAM. PLAN. PERSP., Nov.-Dec. 1999, at 287, 290.

[76] *See, e.g.*, Stewart et al., *supra* note 49, at 2236 (asserting that the pelvic exam is a "medically unnecessary requirement" that "raises important ethical questions").

[77] Harper et al., *supra* note 74, at 13 (citing Food & Drug Admin., *Labeling Guidance for Combination Oral Contraceptives, Prescribing Information, Physician Labeling* (rev. Aug. 1994), *at* http://www.fda.gov; Food & Drug Admin., *Labeling Guidance for Progestin-Only Oral Contraceptives, Prescribing Information, Physician Labeling* (rev. May 1995), *at* http://www.fda.gov).

[78] Harper, et al., *supra* note 74 (citing PLANNED PARENTHOOD FED'N OF AM. NAT'L MED. COMM., MANUAL OF MEDICAL STANDARDS AND GUIDELINES (1996)).

[79] Finer et al., *supra* note 6, at 15; *see also* Jennifer J. Frost & Michele Bolzan, *The Provision of Public-Sector Services by Family Planning Agencies in 1995*, FAM. PLAN. PERSP., Jan.-Feb. 1997, at 6, 8 (stating that fifty-three percent of family planning agencies have instituted policies allowing the pelvic exam to be delayed for women seeking oral

layed pelvic exam if appropriate counseling is provided.[80] Planned Parenthood has recently considered removing the pelvic exam requirement entirely.[81] Such widespread flexibility in and hesitancy about enforcing the requirement raises questions as to its necessity.

Furthermore, there are less invasive alternatives to pelvic exams that can detect the increased risk of developing cervical cancer that the exam is designed to identify. An oral medical and social history is noninvasive and is sufficient to gather most of the information relevant to identifying those women for whom hormonal contraception may not be safe[82] or for whom a pelvic exam may be warranted.[83] For example, it is known that among young adult women, risk factors for eventual development of cervical cancer include early onset of sexual intercourse, an immuno-compromised state such as HIV infection, smoking,[84] infection with an oncogenic type of HPV, or multiple sexual partners.[85] Thus, those who are at risk can be identified by asking patients questions about their medical, sexual, smoking, and drug histories.

In addition to an oral medical and social history, a specimen sample[86] can be collected noninvasively to detect HPV. The vast majority of

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contraceptives); Marjorie R. Sable et al., *Factors Affecting Contraceptive Use in Women Seeking Pregnancy Tests: Missouri, 1997*, FAM. PLAN. PERSP., May-June 2000, at 124, 130.

[80] Finer et al., *supra* note 6, at 15; Memorandum from Jerry Bennett, Acting Deputy Assistant Secretary for Population Affairs, to Regional Health Administrators of Title X programs (June 25, 1993), *available at* http://opa.osophs.dhhs.gov/titlex/pis/opa93-1.pdf (last visited Feb. 1, 2004). On January 11, 2001, OPA issued revised Program Guidelines for Project Grants for Family Planning Services, specifying that deferral of the pelvic exam until after initiation of oral contraceptives was permissible, if judged appropriate by the clinician, for a period of up to three months but no longer than six months. Nat'l Cervical Cancer Coalition, *OPA Issues Revised Title X Guidelines*, *at* http://www.nccc-online.org/fppaps_12.asp (2001) (last visited Feb. 1, 2004).

[81] Harper et al., *supra* note 74, at 13.

[82] For decades, European and developing countries have been safely distributing oral contraceptives without even requiring prescriptions. A pharmacist or other nonphysician screens out women who should not use the pill based on the patient's medical history. Francine M. Coeytaux & Amy Allina, *The Pill Without Prescription: The International Experience*, *in* THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER, *supra* note 67, at 75; *see also* Stewart et al., *supra* note 49, at 2238 (concluding that "[h]ormonal contraception can safely be provided on the basis of careful medical history and blood pressure measurements").

[83] *See infra* Part III.B.3.

[84] After one recent study of the connection between oral contraceptive use and cervical cancer, researchers concluded that an interaction between tar exposure and HPV were the triggering events for development of cervical cancer in oral contraceptive users. Harry Haverkos, *The Cause of Invasive Cervical Cancer Could Be Multifactorial*, 54 BIOMED. & PHARMACOTHERAPY 54, 57 (2000).

[85] Shafer, *supra* note 49, at 68.

[86] A study of 330 young women aged thirteen to twenty who underwent pelvic examination and provided urine samples concluded that pelvic exams in asymptomatic women of this age group were unnecessary, as urine samples could detect most conditions requiring intervention (e.g., sexually transmitted diseases (STDs)), and it was unlikely that any adverse outcome would have resulted had the pelvic exam not been done at that time. Julius Schachter et al., *Routine Pelvic Examinations in Asymptomatic Young Women*, 335 NEW ENG. J. MED. 1847 (1996).

women who develop cervical cancer have HPV,[87] which is detectable by self-collected vaginal swabs.[88] Additionally, HPV DNA tests are available that can be done without a pelvic exam and are *better* than pelvic exams at detecting cervical abnormalities that could indicate a risk of developing cervical cancer.[89] Even among those medical researchers who favor pelvic exams prior to dispensing oral contraceptives, many acknowledge that pap screening largely safeguards against any increase of cervical cancer risk from hormonal contraceptives.[90] Pap screening is possible without a pelvic exam[91] in light of the recent findings of feasibility and accuracy in diagnosis by self-collected vaginal swabs. Screening for HPV is already offered by publicly funded clinics. Thus, implementation of a pap smear alternative would not require additional funding.[92]

Moreover, after pill use has begun, these risk factors can be monitored with follow-up oral medical and social questions and self-collected HPV tests so that the need for annual follow-up pelvic exams for oral contraceptive users is eliminated.[93] Thus, pelvic exams are not *necessary* to determine whether oral contraceptives can be safely prescribed or continued.

3. The Requirement Is Overinclusive

The pelvic exam requirement fails strict scrutiny review because it is overinclusive. Even if pelvic exams do serve their purpose and are warranted for some women, they are not necessary for all women.[94] For instance, women who recently had a pelvic exam from a different provider

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[87] Of women who develop cervical cancer, ninety-three to one hundred percent have HPV. Judith Reichman, *New Pap Smear Guidelines* (*Today*, NBC television broadcast, Feb. 3, 2003) (on file with author); *see also* Jan M. Walboomers et al., *Human Papillomavirus Is a Necessary Cause of Invasive Cervical Cancer Worldwide*, 189 J. PATHOLOGY 12 (1999); Eduardo L. Franco et al., *Epidemiological Evidence and Human Papillomavirus Infection as a Necessary Cause of Cervical Cancer*, 91 J. NAT'L CANCER INST. 506 (1999).

[88] Patti E. Gravitt et al., *Evaluation of Self-Collected Cervicovaginal Cell Samples for Human Papillomavirus Testing by Polymerase Chain Reaction*, 10 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 95 (2001); Celeste Robb-Nicholson, *By the Way, Doctor*, 7 HARV. WOMEN'S HEALTH WATCH 8 (2000) (citing the probable value of self-collected vaginal swab testing for HPV in women who decline pelvic exams); Schachter, *supra* note 86, at 1847.

[89] Robb-Nicholson, *supra* note 88, at 8.

[90] Parazzini et al., *supra* note 49, at 888.

[91] Gravitt et al., *supra* note 88, at 95; Robb-Nicholson, *supra* note 88, at 8.

[92] Dailard, *supra* note 7, at 8.

[93] *See* Reichman, *supra* note 87 (stating that pap smears to detect cervical cancer need not be done yearly for women over thirty who have had three normal pap smears in a row).

[94] The International Planned Parenthood Federation took the position in 1995 that "[p]hysical examination, including breast and pelvic examinations, may be beneficial for certain groups of women as part of their reproductive health care but they are not essential to all women for safe use of oral contraceptives." Stewart et al., *supra* note 49, at 2233 (citing Int'l Planned Parenthood Fed'n, *IMAP Statement on Steroidal Oral Contraception*, 29 IPPF MED. BULL. 1, 1–6 (1995)).

may not need another.[95] Likewise, women without any or with merely insignificant risk factors for developing cervical cancer do not need a pelvic exam to protect their safety.[96] In January 2003, the American Cancer Society modified its suggested pap smear schedule to recommend that women under twenty-one not receive pap smears for cervical cancer screening *at all* until three years after the onset of sexual intercourse.[97]

Furthermore, physicians consider HPV to be essentially a necessary precondition to cervical cancer.[98] The number of women who do not have HPV but will develop cervical cancer is so small that it is economically unjustifiable to perform an expensive cervical cancer detection exam on this group.[99] By this same logic, it is constitutionally unjustifiable to impose such an invasive procedure when so many would not benefit from the exam after a less invasive screen for HPV.[100]

Moreover, though HPV is essentially a necessary precursor to development of cervical cancer, the vast majority of HPV infections do not evolve into cervical cancer.[101] Thus, the requirement of "passing" a pelvic exam is even more overinclusive, as most women who fail the HPV screen will not suffer potential detriments to health as a result of the pill. In fact, research shows that while oral contraceptive use is a risk factor for cervical cancer in women with HPV, there is no connection between oral contraceptives and cervical cancer in women who do not have HPV.[102] Even for women who have HPV, the risk of developing cervical cancer

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[95] In one survey, eighty-three percent of women who went to a new provider for oral contraceptives had received a pelvic exam within the last three years. Harper et al., *supra* note 74, at 15.

[96] For example, ACOG, which initially established the pelvic exam as a prerequisite to oral contraceptives in publicly funded clinics, now states that "[a] pelvic examination is not necessary prior to initiating oral contraceptives in teenagers." Stewart et al., *supra* note 49, at 2233 (citing AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, ORAL CONTRACEPTIVES FOR ADOLESCENTS: BENEFITS AND SAFETY (1999)).

[97] Reichman, *supra* note 87. The rationale for eliminating pap smears in this group of women is that it prevents overly invasive, unnecessary, expensive, and potentially reproduction-detrimental therapies in women in whom ninety percent of low-grade lesions will regress, rather than develop into cancer. *Id.*

[98] There is an extremely high correlation between HPV and cervical cancer development. *See, e.g.*, Walboomers et al., *supra* note 87, at 12; Franco et al., *supra* note 87, at 506.

[99] *See* Shafer, *supra* note 49, at 71–72 (finding that it is not cost-effective to use pelvic exams to screen for cervical cancer in young women who do not possess risk factors).

[100] *Cf.* Craig v. Boren, 429 U.S. 190, 212–14 (Stevens, J., concurring) (noting the overinclusiveness of a statute forbidding the sale of beer to all males under age twenty-one and females under age eighteen on the rationale of increasing traffic safety, where only two percent of males were known to have driven while intoxicated and consumption of alcohol by these males was not prohibited).

[101] Robb-Nicholson, *supra* note 88, at 8; *see also* AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES, *supra* note 55, at 137 (reporting that "[a]lthough millions of women are infected with HPV, only a few will ever develop significant cervical neoplasia").

[102] Wilkinson, *supra* note 72, at 265 (referring to a 2002 study by Sylvia Franceschi and colleagues that found no connection between oral contraceptives and cervical cancer in women who tested negative for HPV).

does not increase until after four years of using oral contraceptives.[103] Because a large number of women who begin taking oral contraceptives will discontinue use shortly thereafter,[104] the pelvic exam requirement is overinclusive even for women with a possible risk of cervical cancer.

Even if oral contraceptive use is causally connected to cervical cancer, the pelvic exam requirement is still overinclusive because any increased risk of developing the disease is extremely small.[105] Furthermore, the mortality rate from cervical cancer in the United States is only one per 100,000 women.[106] Among teenagers aged fifteen to nineteen, the rate of cervical cancer is only one in 500,000, and, when limited to women in this age group who are sexually active (those most likely to be seeking oral contraceptives), one million pelvic exams must be performed to detect one case of cervical cancer.[107] Such low incidence and mortality rates render the required privacy-invading exam overinclusive, particularly since the exam could still be available and encouraged for those who do not object to it.

Under Title X, certain types of tests, such as tests for HIV and other sexually transmitted diseases, are only performed "as indicated."[108] Pelvic exams could also be required "as indicated," according to physician discretion[109] based on risk factors that can be elicited through an oral medical history, medical records, or other less invasive tests.[110] Indeed, in most cases after an abnormal finding, the doctor informs the patient of the increased risks associated with beginning oral contraception and helps the patient make a decision.[111] This process would effectively protect women's safety without the overinclusiveness of the current regulations.

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[103] Moreno et al., *supra* note 49, at 1085; Amy Berrington de Gonzalez et al., *Risk of Cervical Cancer According to Duration of Oral Contraceptive Use*, 360 LANCET 410 (2002); Wilkinson, *supra* note 72, at 265; *see also* Parazzini et al., *supra* note 49, at 887 (1998) (stating excess risk of cervical cancer among oral contraceptive users declines with time since ceasing use and is largely restricted to long-term use).

[104] AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES, *supra* note 55, at 99.

[105] *See, e.g.*, D. A. Edelman & W. A. A. van Os, *Combined Oral Contraceptives and the Risk of Cervical Cancer*, 56 INT'L J. GYNECOLOGY & OBSTETRICS 57, 57 (1997).

[106] *See* Family Health Int'l, *supra* note 52, *at* http://www.fhi.org/en/RH/Pubs/factsheets/OCriskben.htm.

[107] Shafer, *supra* note 49, at 71.

[108] OFF. OF POPULATION AFFAIRS, U.S. DEP'T OF HEALTH & HUMAN SERVS., PROGRAM GUIDELINES FOR PROJECT GRANTS FOR FAMILY PLANNING SERVICES § 8.3 (2001).

[109] Private providers already use this discretionary approach of deciding decide whether a pelvic exam should be performed on a case-by-case basis.

[110] This suggestion has already been made in the context of adolescent females. Shafer, *supra* note 49, at 70.

[111] *See* AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES, *supra* note 55, at 93 (stating that, in the absence of absolute contraindications, "the health care provider should fully explain side effects and risks for all methods [of contraception]" and "the patient's choice of a method of contraception or family planning should be the principal factor for prescribing one [contraceptive method] over another").

The overinclusiveness of the requirement alone is substantial enough to constitute an unjustified infringement on women's fundamental rights.[112] In conjunction with the requirement's lack of necessity and failure to serve its purpose, the overinclusiveness of the pelvic exam requirement is an unconstitutional violation of women's substantive due process rights.

4. The Burden of the Pelvic Exam Requirement Renders It Impermissible Under Strict Scrutiny Review

In *Eisenstadt v. Baird*, the Supreme Court characterized requiring prescriptions for birth control as a "substantial burden" to place on the exercise of the constitutional right of access to contraceptives.[113] Although some argue that oral contraceptives should be available without a prescription,[114] this requirement has not been rendered unconstitutional. The government's interest in protecting women's health is thought to outweigh a woman's right of access to contraception such that the hurdle of visiting a physician to obtain a prescription is a justifiable infringement on her right. However, a prescription merely entails a woman consulting a physician who has deemed access to the drug an acceptable risk.

In contrast, the pelvic exam requirement forces bodily invasion regardless of a physician's opinion. Because bodily integrity, as opposed to convenient access to contraception, is the right countervailing the government's interest, the balance tips in favor of the woman's right. While the government has a sound interest in women's receiving information about the risks of a prescription through consultation with a physician, it has only a weak interest in women undergoing a pelvic exam due to the exam's lack of necessity for protecting women's health. Under *Eisenstadt*, a very strong evidentiary showing is necessary to warrant the additional burden of a pelvic exam beyond the "substantial burden" of obtaining a prescription.[115] When weighed against the government's weak interest in protecting health, given the absence of a link between oral contraceptive use and pelvic exam findings, the requirement's imposition on women's fundamental rights to contraceptive accessibility and bodily integrity is unconstitutional under strict scrutiny.

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[112] The requirement also arguably fails strict scrutiny review because it applies only to the women who obtain oral contraceptives at public clinics. *Cf.* Brenda D. Hofman, Note, *The Squeal Rule: Statutory Resolution and Constitutional Implications—Burdening the Minor's Right of Privacy*, 1984 DUKE L.J. 1325, 1351 (arguing safeguards to protect adolescents from the hazards of oral contraceptives would be underinclusive where they did not apply to adult women using equally hazardous contraceptives).

[113] 405 U.S. 438, 463 (1972) (White, J., concurring).

[114] *See, e.g.*, MEAD, *supra* note 67; Petitti, *supra* note 67, at 77–115.

[115] 405 U.S. at 463 (White, J., concurring); *cf.* Elizabeth A. Silverberg, Note, *Looking Beyond Judicial Deference to Agency Discretion: A Fundamental Right of Access to RU 486?*, 59 BROOK. L. REV. 1551, 1603 n.215 (1994) (arguing that restrictions beyond obtaining a prescription for the chemical contraceptive RU 486 would make access to the drug even more burdensome).

C. Under More Deferential Review, the Pelvic Exam Requirement Remains Unconstitutional

Due to the pelvic exam requirement's confinement within the government's conditional spending programs, it is possible that a court would examine the pelvic exam requirement with an intermediate level of review.[116] Under such a standard, the regulation must be substantially related to serving an important governmental objective.[117] Based on its ineffectiveness at detecting increased risks of adverse effects of oral contraceptives,[118] the pelvic exam requirement is not substantially related to serving its purpose and, therefore, fails intermediate level review.

Although there are fundamental rights at issue, a court may utilize mere rational basis review because the rights affected involve the receipt of public funding.[119] Under rational basis review, the pelvic exam requirement must only be a reasonable way to achieve a legitimate governmental goal.[120] However, because of the lack of connection between oral contraceptives and the risk factors the pelvic exam requirement is designed to detect, the requirement is not even a reasonable way to protect women's health against potential adverse effects of oral contraceptive use. In fact, the exam requirement is irrational: while intended to protect women's health by helping prevent genital cancers, it increases women's health risks generally,[121] resulting in increased incidences of ovarian and endometrial cancer.[122]

IV. Equal Protection Violation

The pelvic exam requirement for access to publicly funded hormonal contraception constitutes an equal protection violation under both disparate treatment and disparate impact analyses. The requirement treats women differently from men and disproportionately affects minority women. It

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[116] *See* Susan Frelich Appleton, *Standards for Constitutional Review of Privacy-Invading Welfare Reforms: Distinguishing the Abortion-Funding Cases and Redeeming the Undue-Burden Test*, 49 Vand. L. Rev. 1, 18, 60 (1996) (discussing the abortion-funding cases' application of rational basis review on grounds that welfare reforms are part of a governmental conditional spending program but arguing that "it is not unrealistic to expect the Court to apply something more than rational-basis review to state manipulations of reproductive choice through the combination of action and inaction embodied in welfare reform").

[117] Craig v. Boren, 429 U.S. 190, 197 (1976).

[118] *See supra* Part III.B.1.

[119] *See, e.g.*, Harris v. McRae, 448 U.S. 297 (1980); Maher v. Roe, 432 U.S. 464 (1977).

[120] Williamson v. Lee Optical, 348 U.S. 483 (1955).

[121] *See supra* Part III.B.1.c.

[122] Because oral contraceptives actually protect against endometrial and ovarian cancer (with pill users experiencing only half the incidence of these diseases as non-pill users), *see supra* text accompanying notes 52 and 66, the deterrent effect of the pelvic exam requirement will result in increased incidences of these cancers. *See infra* Part VII.A.1.

violates women's and minorities' rights to equal protection because the government's determination of who can and cannot exercise the fundamental rights of bodily privacy and access to contraceptives is not justified by a compelling governmental interest. In fact, the requirement is unconstitutional under any level of review: it fails even rational basis review because it increases risks to women's health and because the government can have no legitimate interest in a health care program that creates a caste system.

A. Disparate Treatment Analysis

Government-funded family planning service regulations cause impermissibly disparate treatment of women. Because pelvic exams cannot identify any conditions that are causally connected to or that absolutely contraindicate oral contraceptive use, their only legitimate purpose is the general health care of Title X beneficiaries—detecting sexually transmitted diseases,[123] pelvic inflammatory disease, or cancer.[124] Yet even assuming that the exam effectively serves this purpose, the requirement still violates equal protection.

Equal protection doctrine mandates that a state must treat similarly situated persons alike.[125] However, while women are subjected to invasive preventive care at family planning clinics, men are not.[126] Men are not

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[123] Even if a pelvic exam serves an important governmental objective of protecting public health by detecting STDs, it is still unconstitutional to mandate it prior to receipt of oral contraceptives. STDs are unrelated to the risks of oral contraceptive use and can be detected by less invasive visual exams, urine screens, and serological tests. *See* Shafer, *supra* note 49, at 70–71; Diane R. Blake et al., *Sexually Transmitted Disease Evaluation in Young Women: Can It Be Done Without a Speculum?*, 20 J. ADOLESCENT HEALTH 126 (1997).

[124] The legislative history of the Family Planning Amendments of 1989 acknowledges the importance of Title X clinics in providing for essential preventive care via disease screening. *See* 136 CONG. REC. S13,676 (daily ed. Sept. 25, 1990) (statement of Sen. Kennedy); *id.* at S13,680 (statement of Sen. Packwood).

> [A] central Title X principle is that clients visiting family planning clinics for contraceptive care must be offered related preventive health services. As a result, the program regulations and official guidelines specify a wide range of screening services to be delivered to clients at Title X-supported clinics, including pelvic examinations . . . [and] Pap smears . . . .

ALAN GUTTMACHER INST., FULFILLING THE PROMISE, *supra* note 8, at 23, *available at* http://www.guttmacher.org/pubs/fulfill.pdf.

[125] Plyler v. Doe, 457 U.S. 202, 216 (1982).

[126] The language of the regulations classifies on the basis of gender, specifying the exam requirement only for women. Even if this is not considered a facial gender classification, the invasive requirement for women constitutes disparate treatment of women under the rationale of *Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266 (W.D. Wash. 2001). *Erickson* held that an employee prescription benefit plan, which excluded coverage for prescription contraceptives, constituted disparate treatment of women. *Id.* The "mere facial parity" of the benefit plan's coverage did not preclude a finding of violation of Title VII's prohibition against gender discrimination in employment where benefits carved out from

required to have STD screening or prostate exams (which include rectal exams) to obtain condoms or a prescription for virility drugs such as Viagra, despite the opportunity for preventative health care equivalent to that imposed on women by the pelvic exam.[127] Rather, the regulations impose prostate exams on men only "as appropriate."[128] This discrepancy in treatment under Title X provisions violates women's right to engage in nonprocreative sex, which the Supreme Court has recognized as fundamental.[129] Just as Viagra and condoms[130] enable men to engage in sex at will, with less anxiety about impotence or fear of pregnancy, oral contraceptives allow women, otherwise constrained by the realistic fear of pregnancy,[131] to engage in nonprocreative sex.[132]

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coverage were "uniquely designed for women." *Id.* at 1271.

Additionally, a strong argument exists that because restrictions on access to oral contraceptives uniquely burden women, they should be treated like restrictions that explicitly classify based on gender, even if the regulation's classification is facially neutral. *See* Cass R. Sunstein, *Why the Unconstitutional Conditions Doctrine Is an Anachronism (with Particular Reference to Religion, Speech, and Abortion)*, 70 B.U. L. REV. 593, 618 (1990) [hereinafter Sunstein, *Unconstitutional Conditions Doctrine*] (making this argument in reference to abortion, citing Brief for Nat'l Coalition Against Domestic Violence, Webster v. Reproductive Health Services, 492 U.S. 490 (1989)). Although the Supreme Court in *Geduldig v. Aiello*, 417 U.S. 484 (1974), found an insurance plan's denial of benefits for disability resulting from a normal pregnancy classified not by gender, but by pregnant and nonpregnant persons, it found that "[t]here is no risk from which men are protected and women are not." *Id.* at 496. However, the lack of a requirement for a similar examination for men seeking contraception from a clinic protects men, but not women, from the risks associated with denial of effective contraception. Accordingly, the pelvic exam requirement classifies by gender, rather than by oral contraceptive seekers and non-oral contraceptive seekers, even under the rationale of *Geduldig*. Additionally, because the proportion of women who are pregnant (and therefore affected by the policy in *Geduldig*) is drastically smaller than the proportion of women at Title X clinics who are affected by the pelvic exam requirement, the *Geduldig* policy can be more readily construed as a non-gender-based classification than the pelvic exam requirement.

[127] Anita L. Nelson, *Whose Pill Is It Anyway?*, FAM. PLAN. PERSP., Mar.-Apr. 2000, at 89, 89. Viagra is a drug that temporarily relieves impotence in men. Medicaid, one source of family planning services under Title XIX of the Social Security Act, *see supra* note 2, pays for Viagra for men. ALAN GUTTMACHER INST., THE INSTITUTE'S FUTURE IX: A STRATEGIC PLAN FOR THE ALAN GUTTMACHER INSTITUTE, 1999–2003 9 (2001), *available at* http://www.agi-usa.org/about/strat_plan.pdf (last visited Feb. 1, 2004); Idaho Women's Network, *Reproductive Health and Rights, at* http://www.idahowomensnetwork.org/issues/status_of_women.htm (last visited Feb. 1, 2004).

[128] OFF. OF POPULATION AFFAIRS, *supra* note 108, § 8.3.

[129] *See supra* notes 28–31 and accompanying text.

[130] While condoms also prevent transmission of STDs, they serve the purpose of enabling men to engage in nonprocreative sex with fewer concerns about pregnancy.

[131] Although nonhormonal forms of birth control are available, these methods are significantly less effective and require either cooperation of a male partner or an invasive insertion procedure by a clinician.

[132] *See* Kathryn Kindell, *Prescription for Fairness: Health Insurance Reimbursement for Viagra and Contraceptives*, 35 TULSA L.J. 399, 399, 419 (2000) (arguing that equal protection doctrine requires health insurance plans to cover prescription contraceptives for women if they cover Viagra for men because both drugs serve the same goal of enabling "sex at will").

B. Disparate Impact Analysis

Even if the pelvic exam requirement is not considered an impermissible gender-based classification, it still violates the equal protection rights of women and minorities. To be constitutional as a facially neutral classification, the pelvic exam requirement cannot both have a very disproportionate impact and be motivated by a discriminatory purpose.[133]

1. Disparate Impact

The burden of the pelvic exam requirement falls exclusively on women and disproportionately on minority women.[134] Requiring an embarrassing, uncomfortable exam[135] of only one distinctly identifiable group stigmatizes[136] that group as acceptably subject to humiliation by degrading, systematic processes. This results in a caste system in which women, particularly minority women, are denied dignity for no legitimate purpose.[137] The Fourteenth Amendment prohibits such laws because "no group may be made into second-class citizens."[138] Further, Title X provisions them-

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[133] *See* CHEMERINSKY, *supra* note 26, at 685–86 (combining the holdings of Palmer v. Thompson, 403 U.S. 217 (1971), and Washington v. Davis, 426 U.S. 229 (1976)).

[134] The proportion of minority Title X recipients (60%) is more than double the proportion of minorities in the general population (29%), and the Caucasian proportion of Title X recipients (40%) is roughly half the proportion of Caucasians in the general population (71%), resulting in an approximately four-fold impact on minorities compared to nonminorities. Cynthia Dailard, *Community Health Centers and Family Planning: What We Know*, THE GUTTMACHER REPORT ON PUBLIC POLICY, Oct. 2001, at 6–7, *available at* http://www.guttmacher.org/journals/tgr_archive.html (last visited Feb. 1, 2004).

[135] HOW TO ORGANIZE, *supra* note 51, at 44 (asserting that most women find the pelvic exam to be embarrassing and uncomfortable).

[136] *Cf.* Kenneth L. Karst, *The Supreme Court 1976 Term—Foreword: Equal Citizenship Under the Fourteenth Amendment*, 91 HARV. L. REV. 1, 6 (1977) (discussing stigmatization in the context of equal protection of women). Although rules resulting in stigma upon a group have only been held explicitly impermissible in cases dealing with race, *see, e.g.*, Washington v. Davis, 426 U.S. 229 (1976); Palmer v. Thompson, 403 U.S. 217 (1971); Strauder v. West Virginia, 100 U.S. 303 (1879), the logic applies equally to women. *See infra* Part IV.C (arguing that classifications based on gender carry a risk of stigmatic harm equally dangerous to those based on race, such that gender classifications are adequately suspect to warrant strict scrutiny).

[137] A caste system involves social stratification in which social practices produce obstacles to the development of self-respect in members of the system's lower classes. This phenomenon largely stems from the presence of highly visible but morally irrelevant characteristics (e.g., race or gender) and results in systematic disadvantages and "second-class citizenship" for those in the lower classes. Cass R. Sunstein, *The Anticaste Principle*, 92 MICH. L. REV. 2410, 2428–35 (1994).

[138] *Id.* at 2428–29, 2435; *see* Strauder v. West Virginia, 100 U.S. 303 (1880) (holding as impermissible processes that result in the "branding" of inferiority or stigmatization of a racial group such that a caste system develops); Skinner v. Oklahoma, 316 U.S. 535 (1942) (holding that the right to procreate is too fundamental to be distributed according to a system of constitutional caste); *see also* Kathleen Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1415, 1497 (1989) (arguing the unconstitutional conditions doctrine is concerned with preventing a constitutional caste system by protecting against "hierarchy among classes that, without the government intervention, would make the *same* choice").

selves prohibit this result because they specifically mandate that services be provided in a manner which protects the dignity of the individual.[139]

a. Gender Impact

Restrictions on access to oral contraceptives uniquely burden women.[140] "Control of reproduction is the sine qua non of women's capacity to live as equal people."[141] The pelvic exam requirement leaves women who decline the exam without effective control over their reproduction, forcing them to rely on their partners. As a result of this deprivation of control, which is not experienced by men, women must cope with the psychological burdens of vulnerability and the physical, emotional, and financial burdens of pregnancy and motherhood or abortion. As acknowledged in *Erickson v. Bartell Drug Co.*, "the adverse economic and social consequences of unintended pregnancies fall most harshly on women and interfere with their choice to participate fully and equally in 'the marketplace and the world of ideas.'"[142]

As a result, women are burdened with economic difficulties in a vicious cycle that creates and maintains a caste system. The stigma of caste is manifest in the derogatory term "welfare queen,"[143] which refers to poor women with children who have become dependent upon public support. Another manifestation of this stigma is characterization as a "housewife," which carries strong connotations of inferiority among many circles of society.[144] For those who are forced into the role of "housewife" by an unintended pregnancy, derailed goals, and economic reliance on male partners, this has as much sting of inferiority[145] as does the differential treatment of racial minorities found by the Supreme Court to create an

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[139] 42 C.F.R. § 59.5(3) (2002).

[140] *See* Sunstein, *Unconstitutional Conditions Doctrine*, *supra* note 126, at 618 (citing Brief for National Coalition Against Domestic Violence as Amicus Curiae Supporting the Appellees, Webster v. Reproductive Health Servs., 492 U.S. 490 (1989) (No. 88-605)).

[141] Law, *supra* note 60, at 1028.

[142] 141 F. Supp. 2d 1266, 1273 (W.D. Wash. 2001) (quoting Stanton v. Stanton, 421 U.S. 7, 14–15 (1975)); *see also* KRISTINE M. BABER & KATHERINE R. ALLEN, WOMEN AND FAMILIES: FEMINIST RECONSTRUCTIONS 102 (1992) (observing that "the responsibility of bearing and caring for children has limited women's autonomy and ability to participate in activities that enhance their personal development and their social and economic status").

[143] *See* Appleton, *supra* note 116, at 18 (referring to society's perception of the "welfare queen" as the "least deserving of the poor"); DOROTHY ROBERTS, KILLING THE BLACK BODY: RACE, REPRODUCTION, AND THE MEANING OF LIBERTY 17, 111 (1997); Catherine Albiston, *The Social Meaning of the Norplant Condition: Constitutional Considerations of Race, Class, and Gender*, 9 BERKELEY WOMEN'S L.J. 9, 17 (1994).

[144] *See, e.g.*, Ralph Gardner, Jr., *Mom vs. Mom*, N.Y. MAG., Oct. 21, 2002, at 21 (citing examples of children embarrassed by their mother's stay-at-home status).

[145] *See id.* (discussing one nonworking mother's feelings of "insuperiority" and the desire of the nonworking woman to "have something that's a reflection of her as an individual—a label that says she's a capable, creative person who knows about more than just baby formula or after-school programs").

impermissible brand of inferiority and implied caste system.[146] As more and more women choose to have careers, those who are unemployed are no longer the norm and are increasingly viewed as inferior because of their economic dependence. Consequently, deprivation of access to effective contraception results in a type of caste system in which women who are financially dependent, nonworking mothers are relegated to the lower castes. Women should not be stigmatized as inferior by being forced into roles which they do not desire.

Strauder v. West Virginia[147] supports the proposition that the processes which cause the stigmatization of one group to such an extent that a caste system develops are impermissible under equal protection doctrine.[148] In *Skinner v. Oklahoma*,[149] the Supreme Court held that the right to procreate is too fundamental to be distributed according to a caste system[150] and later, in *Carey v. Population Services International*, that the right to contraceptives should be viewed as part of the "constitutionally protected right of decision in matters of childbearing that is the underlying foundation of the holdings in *Griswold*, *Eisenstadt v. Baird*, and *Roe v. Wade*."[151] Taken together, these cases indicate that it is constitutionally impermissible for the fundamental right of access to contraceptives to be distributed in a manner which results in inferiority of one group. The reduced access to oral contraceptives caused by the pelvic exam requirement results in the stigmatization of women as inferior and therefore violates equal protection doctrine.

b. Racial Impact

The pelvic exam requirement also has a disparate impact on racial minorities. Because economic status is closely linked with race and ethnicity in the United States, patients of publicly funded clinics are disproportionately from racial and ethnic minority groups.[152] Minority women are also more likely to depend specifically on publicly funded family planning clinics for their contraceptive services.[153]

Additionally, minority women are more likely to experience contraceptive failure, rendering the availability of highly effective contraception

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[146] *See supra* note 136.

[147] 100 U.S. 303, 308 (1879).

[148] *See supra* text accompanying note 136 (explaining why the rationale of *Strauder* applies to women as well as racial minorities).

[149] 316 U.S. 535 (1942).

[150] Sullivan, *supra* note 138 at 1498.

[151] 431 U.S. 678, 688–89 (1977).

[152] *See supra* note 134.

[153] One study found that 75% of women seeing private doctors and HMOs were non-Hispanic white, compared to only 42% at non-Title X public clinics and 57% at Title X clinics. Of women seeing private doctors, 13% were non-Hispanic black, compared to 24% at public clinics. And 9% of women seeing private doctors were Hispanic, compared to 26% at non-Title X public clinics and 15% at Title X clinics. Frost, *supra* note 10 at 10.

particularly important.[154] Denying hormonal contraception for refusal to submit to pelvic exams is perhaps most detrimental to African American women, who may be particularly vulnerable to their male sexual partners' contraception decisions.[155] Relegating women who refuse pelvic exams and cannot afford private physicians to contraceptive methods with significantly lower efficacy rates will result in many more unintended pregnancies for minority women than for nonminority women. This effect exacerbates the disparate impact on minority women because there are already disproportionately more minority women who utilize publicly funded clinics.

In addition to disproportionately burdening minorities, the pelvic exam requirement implies their inferiority within a caste system. The mandatory exam is a surcharge that women utilizing Title X clinics must pay in order to exercise their right to contraceptive access.[156] The fourfold impact of the requirement upon minorities over Caucasians[157] renders it largely a requirement for minority women. "To attach a surcharge to the price that a discrete group of [women] . . . must pay to exercise a constitutional right" is "to create a system of constitutional caste and relegate that group to the lower levels."[158] Thus, requiring a pelvic exam as a prerequisite to oral contraceptives for Title X recipients violates the Equal Protection Clause.

2. Discriminatory Purpose Behind the Pelvic Exam Requirement

In addition to its disparate impact, the pelvic exam requirement constitutes an equal protection violation because evidence points to discriminatory purposes[159] behind the regulation. Because our society has a long history of discrimination against women and minorities, it is likely that many laws with a discriminatory impact were motivated by a discriminatory purpose.[160] Compelling arguments have been made that govern-

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[154] ALAN GUTTMACHER INST., FULFILLING THE PROMISE, *supra* note 8, at 48, *available at* http://www.guttmacher.org/pubs/fulfill.pdf.

[155] *See* Sable et al., *supra* note 79, at 124 (citing K. Libbus & C.A. Arps, *Beliefs Related to the Use of Oral Contraceptives by African-American Women*, 9 J. NAT'L BLACK NURSES ASS'N 29 (1997)).

[156] *See infra* Part V.D.

[157] *See supra* note 134.

[158] Lynn A. Baker, *The Prices of Rights: Toward a Positive Theory of Unconstitutional Conditions*, 75 CORNELL L. REV. 1185, 1251 (1990).

[159] The discriminatory purpose test articulated in *Personnel Administrator of Massachusetts v. Feeney* requires that to be impermissible a regulation must be "selected or reaffirmed . . . at least in part 'because of,' not merely 'in spite of,' its adverse effects upon an identifiable group." 442 U.S. 256, 279 (1979).

[160] CHEMERINSKY, *supra* note 26, at 685 (citing David Strauss, *Discriminatory Intent and the Taming of* Brown, 56 U. CHI. L. REV. 935 (1989)); *see also* Frontiero v. Richardson, 411 U.S. 677, 682, 684 (1973) (plurality opinion) (noting that gender classifications "are inherently suspect and must therefore be subjected to close judicial scrutiny" in part because "[t]here can be no doubt that our Nation has had a long and unfortunate history of sex discrimination").

ment programs which exert control over women's reproduction, either by facilitating use of or restricting access to birth control, are intended to oppress women, especially minorities.[161] The requirement of a pelvic exam despite a lack of evidence of any connection between oral contraceptive use and health-related factors detectable by the exam also suggests that there may be an illegitimate purpose behind the requirement.

a. Discriminatory Purpose with Respect to Women

A strong argument can be made that the pelvic exam requirement was created with a purpose discriminatory to women. The requirement may stem from a paternal effort to make decisions for women, presuming them incapable of weighing the risks and benefits of oral contraception without an exam.[162] Alternatively, the pelvic exam requirement may have been intended to degrade women. Some scholars argue that history demands skepticism of rules based on women's biological differences from men because "less than a century ago 'doctors and scientists were generally of the view that a women's [sic] intellect, her capacity for education, for reasoning . . . was biologically limited.'"[163] Additionally, the "protection" of women through use of the "pedestal/cage" has historically been key in the oppression of women,[164] and biological differences have served as a prime justification for the subjugation of women.[165]

The constructs of law have historically supported the dominance of men and subservience of women[166] by creating separate spheres for the sexes and enacting limits on women's power to control reproductive capacity.[167] When legislatures' interest in enacting laws is control over women's decisions and actions, these "male-dominated governmental bodies echo the

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[161] *See generally* ROBERTS, *supra* note 143 (documenting such government programs' effects on black women and black communities). *See also infra* Parts IV.B.2.a, IV.B.2.b.

[162] *See* Stewart et al., *supra* note 49, at 2236 (stating that in areas of medical services other than women's reproductive care, it would not be considered appropriate to withhold a prescription from someone who has been informed of the risks involved and chooses to forego screening for an unrelated condition). *Cf.* Appleton, *supra* note 116, at 36–37 & nn.214–215 (discussing the impermissibility of welfare programs, such as Norplant bonuses, that constitute "paternalistic effort[s] to help vulnerable women make sound family choices").

[163] Law, *supra* note 60, at 1033 (quoting Wendy Webster Williams, *The Equality Crisis: Some Reflections on Culture, Courts, and Feminism*, 7 WOMEN'S RTS. L. REP. 175, 199 (1982)).

[164] *Id.* at 957 (citing BARBARA ALLEN BABCOCK ET AL., SEX DISCRIMINATION AND THE LAW: CAUSES AND REMEDIES 26–53 (1973).

[165] Nadine Taub, Book Review, 80 COLUM. L. REV. 1686, 1687 (1980) (reviewing CATHARINE MACKINNON, SEXUAL HARASSMENT OF WORKING WOMEN: A CASE OF SEX DISCRIMINATION (1979)).

[166] *See* Barbara Kirk Cavanagh, Note, *"A Little Dearer Than His Horse": Legal Stereotypes and the Feminine Personality*, 6 HARV. C.R.-C.L. L. REV. 260 (1971) (summarizing the history of the use of the law to assure the dependency of women); Law, *supra* note 60, at 964.

[167] Law, *supra* note 60, at 958.

rationale behind laws that once barred women from equal protection in the paid labor force and political and civic affairs."[168] The Supreme Court has specifically acknowledged this country's "long and unfortunate history of sex discrimination."[169] In *United States v. Virginia*[170] the Court found that a gender classification clearly resulting in greater benefits for men would be easily defended if women were established as fully equal to men, but the historical treatment of women as inferior to men made it likely that the classification was "a witting or unwitting device for preserving tacit assumptions of male superiority."[171] A lack of gender equality has also impacted issues of women's health, which historically have been largely ignored within the Department of Health and Human Services ("HHS").[172]

In addition to our country's history of discrimination against women, the legislative history of a particular regulation can also serve as evidence of discriminatory purpose.[173] At the time the pelvic exam requirement was created,[174] family planning program administrators knew that oral contraceptives were not causally connected with genital cancer.[175] A legitimate, nondiscriminatory reason behind the requirement thus cannot be inferred from the requirement's creation.[176] It is also significant that pelvic exams are not required of women seeking care from private providers and that the requirement is a questionable interpretation of the FDA's recommendation that pelvic exams "should" be performed.[177] The

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[168] Johnsen, *supra* note 41, at 203–04 (citing as evidence Hoyt v. Florida, 368 U.S. 57 (1961) (women exempted absolutely from participation in jury service); Breedlove v. Suttles, 302 U.S. 277 (1937) (women who did not register to vote exempted from poll tax); Muller v. Oregon, 208 U.S. 412 (1908) (restrictions placed on women's working hours outside the home); Bradwell v. Oregon, 83 U.S. 130 (1872) (women excluded from receiving licenses to practice law)).

[169] Frontiero v. Richardson, 411 U.S. 677, 684 (1973) (plurality opinion).

[170] 518 U.S. 515 (1996).

[171] *Id.* at 535 n.8.

[172] Silverberg, *supra* note 115, at 1596–99 (citing examples such as failing to include women in research studies, permitting drugs not adequately tested for safety in women to be prescribed to women, underfunding research of women's diseases, providing greater accessibility to diagnostic procedures and greater availability of therapeutic intervention to men, giving disparate diagnoses of and attention to health complaints of women and men, and failing to include women in decisionmaking processes surrounding drugs for women).

[173] Dorothy E. Roberts, *The Future of Reproductive Choice for Poor Women and Women of Color*, 14 WOMEN'S RTS. L. REP. 305, 307 (1992) (citing CATHARINE A. MACKINNON, FEMINISM UNMODIFIED 7, 97 (1987)); Law, *supra* note 60, at 957–62); *see also* Meredith Blake, *Welfare and Coerced Contraception: Morality Implications of State Sponsored Reproductive Control*, 34 U. LOUISVILLE J. FAM. L. 311, 311–17 (1995-1996).

[174] *See infra* note 275 and accompanying text.

[175] *See* HOW TO ORGANIZE, *supra* note 51, at 49.

[176] Furthermore, such a purpose is impossible to establish for the 2001 decision to maintain the pelvic exam requirement because there is no legislative history surrounding that decision. "OPA's interpretive guidance did not require clearance by other agencies within the government or publication in the Federal Register because it does not establish new policy." Nat'l Cervical Cancer Coalition, *supra* note 80, *at* http://www.nccc-online.org/fppaps_12.asp.

[177] *See infra* notes 275–277 and accompanying text.

absence of any legitimate justification makes it probable that the true purpose behind the requirement was impermissible discrimination. This likelihood of a discriminatory purpose, in conjunction with the vastly disparate impact of the requirement on women, provides grounds for invalidation of the requirement as a violation of equal protection doctrine.

In *Planned Parenthood v. Casey*, the Supreme Court upheld patronizing informed consent rules for women seeking abortions.[178] However, the decision of whether or not to obtain an abortion affects not only a woman's life but also arguably a fetal life. In such a situation, women's authority to make decisions is less clear than in the contraception-seeking situation, in which the decision by a woman affects only her *own* life. In the absence of a viable fetal life, the government's interest does not outweigh a woman's right to control reproduction such that it justifies burdening her reproductive decisions.[179] Paternalism is especially inappropriate with respect to a woman seeking contraception for whom, unlike the pregnant women considered by *Casey*, there is not the emotional influence of an unwanted pregnancy which could arguably influence her judgment.

b. Discriminatory Purpose with Respect to Minorities

Many laws have been created with the discriminatory purpose of exercising control over the reproductive decisions of minority groups.[180] One possible motivation is the perpetuation of minorities' poverty by enlarging already financially disadvantaged families.[181] At the other end of the spectrum, legislators and providers may paternalistically presume that minorities are incapable of making the "right" decisions.[182] In particular, some health care providers consider minority women unable to follow an oral contraceptive regimen with enough compliance for its use to be effective.[183] A plausible theory of discriminatory governmental purpose is that the lack of abortion services under Title X,[184] in addition to the lack

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[178] 505 U.S. 833 (1992).

[179] Roe v. Wade, 410 U.S. 113 (1973).

[180] *See* ROBERTS, *supra* note 143 at 4 (describing "a long experience of dehumanizing attempts to control Black women's reproductive lives" through the "systematic, institutionalized denial of reproductive freedom [that] has uniquely marked Black women's history in America").

[181] *See id.* at 210, 235 (discussing legislators' enacting caps on the number of children for which a woman may receive governmental assistance while acknowledging that such caps are not known to deter poor women from having additional children). By simultaneously enacting policies that increase unwanted pregnancies, do not fund abortions, and limit governmental assistance, the government appears to be perpetuating the poverty of families subject to Title X and other welfare regulations.

[182] For example, they may want to encourage sterilization (rather than temporary forms of oral contraception) for poor minority women because they believe such women are unfit mothers who should not have children at all. *See* Albiston, *supra* note 143, at 19.

[183] *See* Roberts, *supra* note 173, at 310 n.32.

[184] 42 U.S.C. § 300a-6 (2000) (prohibiting Title X funds from being used for abortions or abortion-related services).

of effective contraception (for those who decline a pelvic exam), is intended to cause poor women to resort to sterilization,[185] which, unlike abortion, *is* covered by Title X funds.[186]

The myriad of historical examples of discrimination against minorities and legislation implicating reproductive issues for minorities[187] make a racially discriminatory purpose to the pelvic exam requirement highly probable. During the slave trade in the United States, the law allowed female slaves to be sexually exploited for their capacity to produce more slaves, while simultaneously separating them from their children.[188] In its early years, contraception distribution was associated with eugenics and racial genocide,[189] and, as acknowledged in current Title X provisions themselves,[190] government-sponsored programs of the 1960s and 1970s coerced thousands of women, who were vastly disproportionately minorities, into sterilization.[191] Legislative proposals and mainstream media have reflected discriminatory reproductive policy goals by suggesting Norplant should be required as a condition of probation or receipt of welfare benefits,[192] which affect minority women more frequently than nonminority women.[193]

Law enforcement has exhibited a similarly discriminatory intent with respect to minorities' reproductive rights. For example, officers in Charleston, South Carolina, arrested forty-two African American women and only one non-African American woman under a policy of prosecut-

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[185] *See* Blake, *supra* note 173, at 338–39 (citing Laurie Nsiah-Jefferson, *Reproductive Laws, Women of Color, and Low-Income Women*, *in* REPRODUCTIVE LAWS FOR THE 1990S 23, 47 (1989), for the proposition that "subtle coercion by care providers may often confirm the view of the welfare patient that sterilization is the only alternative to impersonal, degrading reproductive health care that often denies access to safe, effective contraception or to abortion"); ROBERTS, *supra* note 143, at 235.

[186] That sterilization is covered by Title X funds and is provided upon demand, despite the fact that it entails risks greater than those of oral contraceptives alone suggests a discriminatory desire to stop the reproduction of Title X recipients, who are disproportionately racial minorities. Blake, *supra* note 173, at 326–28.

[187] *See* Suzanne Sangree, *Control of Childbearing by HIV-Positive Women: Some Responses to Emerging Legal Policies*, 41 BUFF. L. REV. 309, 319–23 (1993) (discussing ways in which "[t]he government has . . . sought to exert control over childbearing through welfare and [M]edicaid funding schemes that shape the reproductive choices of poor women, a class which is disproportionately comprised of women of color and disabled women").

[188] ROBERTS, supra note 143, at 23–28, 33; *see also* Sangree, *supra* note 187, at 319–23.

[189] ROBERTS, *supra* note 143, at 7, 70–81, 98–103; Vanessa Northington Gamble, *Race, Class, and the Pill: A History*, *in* THE PILL: FROM PRESCRIPTION TO OVER THE COUNTER, *supra* note 67, at 30–35.

[190] 42 U.S.C. § 300a-8 (2000) (specifically prohibiting coercion of sterilization procedures in Title X clinics).

[191] ROBERTS, *supra* note 143, at 89–98; Blake, *supra* note 173, at 313–17; *see also* Sangree, *supra* note 187, at 324–25 (discussing disproportionate sterilization of Native Americans, Puerto Ricans, and African Americans).

[192] Albiston, *supra* note 143, at 11; Blake, *supra* note 173, at 318–19.

[193] ROBERTS, *supra* note 143, at 3–4, 104–12.

ing pregnant women whose prenatal tests indicated use of crack cocaine.[194] Similarly, health care professionals in Florida reported African American, substance-abusing, pregnant women to law enforcement officials ten times more often than their white counterparts, despite the fact that white women's rate of substance abuse was actually higher.[195] The mere existence of a policy to prosecute pregnant women who use crack, but not, for example, alcohol, is itself evidence of discrimination with respect to reproduction by minorities: alcohol use during pregnancy is far more injurious to the fetus but also more prevalent among white women.[196] Finally, courts' actions concerning reproduction indicate a possible discriminatory intent against minority women.[197]

The lack of a record to indicate a permissible purpose behind creating or maintaining the pelvic exam requirement, the long history of discrimination against minorities with respect to reproductive policies, and the requirement's failure to serve a purpose relevant to oral contraceptive use make a discriminatory purpose behind the requirement highly probable. In conjunction with its disparate impact upon minorities, this likely discriminatory purpose provides grounds for invalidation of the requirement as an equal protection violation.

C. The Pelvic Exam Requirement Is Unconstitutional on Equal Protection Grounds Under All Standards of Review

Strict scrutiny is the appropriate level of review for an equal protection analysis concerning the race and gender discrimination inherent in the pelvic exam requirement. There is a fundamental right involved,[198] and there are violations arguably based on race.[199] Additionally, while gender-based classifications are generally subject to an intermediate level

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[194] *Id.* at 164–72.

[195] *Id.* at 175.

[196] *Id.* at 177; Albiston, *supra* note 143, at 15; *see also* Deborah A. Frank et al., *Growth, Development, and Behavior in Early Childhood Following Prenatal Cocaine Exposure: A Systematic Review*, 285 JAMA 1613, 1613, 1617, 1620–21, 1624 (2001) (discussing the situation in South Carolina and concluding that cocaine exposure has not been associated with harm to the fetus that would "justify policies that violate the usual canons of medical ethics and civil liberties").

[197] *See* Johnsen, *supra* note 41, at 203 n.81 (citing, as an example of a reason to be concerned about fair treatment of minorities regarding reproductive decisions, a national survey indicating that eighty-one percent of documented court orders compelling pregnant women to undergo medical treatment (such as cesarean sections, intrauterine transfusions, and hospital detention) involved women who were African American, Asian, or Hispanic); Albiston, *supra* note 143, at 11 (citing judges' imposition of Norplant as a condition of probation, which is more likely to affect minority women).

[198] United States v. Carolene Prods. Co., 304 U.S. 144, 152 n.4 (1938) (holding that laws infringing upon fundamental rights may be subject to "more searching judicial inquiry").

[199] Even though the requirement is facially neutral as to race, it is subject to strict scrutiny because of the likely discriminatory purpose discussed *supra* in Part IV.B.2.b. CHEMERINSKY, *supra* note 26, at 682.

of scrutiny,[200] if, in addition to a disparate impact on one gender, the purpose of the law is to stigmatize that gender (as opposed to merely perpetuating gender roles), the law should be subject to strict scrutiny.[201]

The purpose of strict scrutiny review is to ensure equal protection of the laws through "'smok[ing] out' illegitimate uses" of suspect classifications "by assuring that the legislative body is pursuing a goal important enough to warrant use of a highly suspect tool."[202] Without thoroughly examining the justification for race- or gender-conscious measures, there is no way to determine which classifications are motivated by malicious intent.[203] The gender classification utilized in the regulations requiring the pelvic examination is suspect: historical discrimination against minorities and women, particularly within the context of reproductive decisionmaking rights, creates valid skepticism about this classification's purpose.[204]

In *J.E.B. v. Alabama ex rel. T.B.*, the Supreme Court left open the possibility that gender classifications should be subject to strict scrutiny when it declined to decide whether gender classifications were inherently suspect.[205] The Court did acknowledge that our country's history of sex discrimination warrants heightened scrutiny for gender-based classifications.[206] Then, in *United States v. Virginia*, the Court applied an especially rigorous version of intermediate scrutiny, requiring a showing of an "exceedingly persuasive justification" in order for a gender-based classification to be upheld.[207] The Court further asserted that the "demanding" burden of justification rested on the state and could not be satisfied with a "hypothesized" justification.[208]

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[200] Craig v. Boren, 429 U.S. 190 (1976). *But see* J.E.B. v. Alabama *ex rel.* T.B., 511 U.S. 127, 137 n.6 (1994) (suggesting that intermediate level scrutiny is the *minimum* standard for assessing a gender-based classification).

[201] In *City of Richmond v. J.A. Croson Co.*, the Supreme Court employed strict scrutiny to review a race-based affirmative action policy in part because of the stigma inflicted by race-based classifications. 488 U.S. 469, 493 (1989). Because of their similar stigma, gender-based classifications should also be reviewed under strict scrutiny. John Calotto, Note, *Strict Scrutiny for Gender, via* Croson, 93 COLUM. L. REV. 508, 539 (1993). There are powerful analogies between race- and gender-based discrimination, as both women and minorities have been subject to oppression, are defined by highly visible, immutable characteristics, are economically disadvantaged in comparison to men and whites, respectively, and have a history of exercising limited political power. Law, *supra* note 60, at 963–64.

[202] *Croson*, 488 U.S. at 493.

[203] *Id.*

[204] *See* McCleskey v. Kemp, 481 U.S. 279, 322 (1987) (Brennan, J., dissenting) (arguing that statistical evidence of race discrimination in the administration of the death penalty, when coupled with a history of race discrimination in the jurisdiction, is enough to cause a petitioner's death sentence to violate the Eighth Amendment because, since Furman v. Georgia, 408 U.S. 238 (1972), "the Court has been concerned with the *risk* of the imposition of an arbitrary sentence, rather than the proven fact of one").

[205] 511 U.S. 127, 137, n.6 (1994).

[206] *Id.* at 136.

[207] 518 U.S. 515, 534 (1996) (holding that the state violated the Equal Protection Clause because it failed to show an "exceedingly persuasive justification" for excluding women).

[208] *Id.* at 533.

Furthermore, just as classifications based on race have been subjected to strict scrutiny review because of their "danger of stigmatic harm,"[209] classifications based on gender carry an equivalent risk. Based on the high visibility and immutability of sex characteristics, the Supreme Court has found gender comparable to race in warranting strict scrutiny.[210] Gender should qualify as a suspect classification,[211] particularly in regards to the pelvic examination requirement: HHS and the FDA have historically ignored issues of women's health, women have historically been oppressed by our society, and women are a discrete group defined by immutable physical traits.

Strict scrutiny is especially appropriate in the case of the pelvic exam requirement because the fundamental rights of bodily privacy and access to contraceptives are involved.[212] In *Eisenstadt v. Baird*, Justice White stated:

> Due regard for protecting constitutional rights requires that the record contain evidence that a restriction on distribution of [contraceptives] is essential to achieve the statutory purpose .... Given *Griswold v. Connecticut* ... and absent proof of the probable hazards of using [contraception,] ... to sanction a medical restriction upon distribution of a contraceptive not proved hazardous to health would impair the exercise of the constitutional right.[213]

Therefore, the pelvic exam requirement should be reviewed under strict scrutiny for evidence that this restriction on distribution of oral contraceptives is essential to achieve the goal of protecting women's health. However, if a reviewing court applies the principles of stare decisis, it will likely employ intermediate level review.[214] It is even possible that the

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[209] City of Richmond v. J.A. Croson Co., 488 U.S. 469, 493 (1989).

[210] Frontiero v. Richardson, 411 U.S. 677, 686 (1973) (plurality opinion).

[211] For an argument that all reproductive health legislation should be subject to strict scrutiny, see Ruth Colker, *An Equal Protection Analysis of United States Reproductive Health Policy: Gender, Race, Age, and Class*, 1991 DUKE L.J. 324, 325 (1991). See Law, *supra* note 60, for an argument that laws governing reproductive biology should be subject to heightened scrutiny "to ensure that (1) the law has no significant impact in perpetuating either the oppression of women or culturally imposed sex-role constraints on individual freedom or (2) if the law has this impact, it is justified as the best means of serving a compelling state purpose." *Id.* at 1008–09.

[212] It has also been argued that strict scrutiny should be utilized for "any government benefit condition whose primary purpose or effect is to pressure recipients to alter a choice about exercise of a preferred constitutional liberty in a direction favored by government." Sullivan, *supra* note 138, at 1499–1500.

[213] 405 U.S. 438, 464 (1972) (White, J., concurring).

[214] *See, e.g.*, United States v. Virginia, 518 U.S. 515 (1996); Craig v. Boren, 429 U.S. 190, 197 (1976).

court will utilize only rational basis review because the limitation of rights only occurs where women have benefited from federal funds.[215]

The result is the same regardless of the level of review: the requirement is unconstitutional. For the reasons discussed under the substantive due process violation analysis above, the pelvic exam requirement fails strict scrutiny: it is unnecessary because less invasive methods can protect women's health equally well, it is overly broad, and it does not serve its purpose of protecting the health of women.[216] The requirement fails intermediate level review because it is not substantially related to serving its important governmental objective of protecting women's health from preventable adverse effects of oral contraceptive use, nor, alternatively, is it substantially related to serving the important objective of providing preventive health services to Title X beneficiaries. It is vastly underinclusive in its failure to provide preventive health services to male beneficiaries, unduly burdens female beneficiaries, and creates a caste system in which the government has no substantial (or even legitimate) interest. The pelvic exam requirement fails rational basis review because not only is it not rationally related to the objective of protecting women's health from preventable adverse effects of oral contraceptive use because it increases risks to women's health but the government also has no legitimate interest in a system of preventive health care which creates a caste system.

V. Unconstitutional Condition on Exercise of the Right To Use Contraception

The basic premise of the unconstitutional conditions doctrine[217] is that "the government may not deny a benefit to a person because [s]he exercises a constitutional right."[218] The pelvic exam requirement places a condition that is unconstitutional (waiving the right to bodily integrity) on the exercise of women's privacy right to use contraception.[219]

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[215] *See* Maher v. Roe, 432 U.S. 464 (1977); Harris v. McRae, 448 U.S. 297 (1980).

[216] *See supra* Part III.B.

[217] It is sometimes argued that the unconstitutional conditions doctrine is an anachronism performing a function fully served by the standard process of reviewing the right infringed upon by a challenged regulation in light of the governmental interest it serves under the appropriate standard of review. *See generally* Sunstein, *Unconstitutional Conditions Doctrine*, *supra* note 126. However, analysis of the pelvic exam requirement under this doctrine is useful to illuminate the theory underlying the doctrine and the arguments of waivable rights and governmental power to limit benefits. More importantly, the doctrine is still applied by courts and would likely prove important to invalidate the pelvic exam requirement because it is not a "blanket restriction," as it applies only to individuals benefiting from federal spending.

[218] Chemerinsky, *supra* note 26, at 946 (quoting Regan v. Taxation with Representation of Wash., 461 U.S. 540, 545 (1983)).

[219] While only the *recipient*, not the beneficiary, of federal funds has standing to challenge conditional spending, there are situations in which a recipient might assert a claim on behalf of the beneficiaries it serves. For example, a university receiving Title X funds has an interest in promoting the general health of and contraceptive use by its students.

A. Governmental Denial of Benefits to Women Who Exercise Their Constitutional Bodily Privacy Right

Bodily privacy is a constitutional right[220] that is clearly infringed upon by intrusive pelvic exams. Thus, when women decline pelvic exams they are exercising their constitutional rights. Government-subsidized birth control is a benefit[221] received by those who qualify under financial status requirements.[222] Thus, refusing to dispense government-subsidized birth control to a woman because she declines a pelvic exam is governmental denial of a benefit to someone who exercises a constitutional right. This is prohibited by the doctrine of unconstitutional conditions.

B. Coercion To Waive Bodily Privacy Rights in Exchange for Exercising Constitutional Rights to Reproductive Autonomy and Access to Contraception: Distinguished from the Abortion Funding Cases

The pelvic exam requirement has been analogized to medical practitioners holding effective contraception hostage until a woman submits to the invasive exam.[223] Although within the context of abortion the right to reproductive autonomy does not "carr[y] with it a constitutional entitlement to the financial resources to avail [oneself] of [it],"[224] the pelvic exam requirement is distinguishable. The exercise of contraceptive rights for those lacking financial resources is possible with federal funds but requires allowing the government to invade bodily privacy. In the abortion context, the exercise of rights for the "indigent" is not possible with federal funds because the government does not provide abortion services. Thus, abortions do not involve coerced decisions because there is no receipt of a benefit that is conditioned on relinquishment of a constitutional right: either a woman can afford to obtain an abortion from a non-federally funded source or she cannot get one at all. In contrast, the choice surrounding the pelvic exam requirement involves more than the availability of funds: it involves deciding between foregoing hormonal contraceptives

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Thus, it may assert their constitutional rights in seeking invalidation of the exam requirement due to its deterrent effect on use of the university's health services.

[220] *See, e.g.*, Winston v. Lee, 470 U.S. 753, 761 (1985); Rochin v. California, 342 U.S. 165, 172 (1952).

[221] Whether government-subsidized birth control is a benefit or an entitlement is arguable and will be discussed further, *see infra* Part V.C., but benefit status is used here under a conservative approach to make the strength of the argument even more apparent.

[222] Although Title X family planning services are available to women of all economic strata, subsidies vary depending on patients' finances. 42 U.S.C. §§ 300 to 300a-6a (2003). Medicaid requires women to meet financial requirements to qualify for its benefits. 42 U.S.C. § 1396 (2000).

[223] Nelson, *supra* note 127, at 89.

[224] Harris v. McRae, 448 U.S. 297, 316 (1980) (upholding the Hyde Amendment, which prohibits using federal Medicaid funds to perform abortions, except in cases of rape, incest, or endangerment of the mother's life).

or relinquishing bodily privacy. The cost of an abortion for both the poor and the wealthy in the abortion funding cases (*Harris v. McRae*,[225] *Maher v. Roe*,[226] and *Rust v. Sullivan*[227]) is purely financial; with the pelvic exam requirement, the cost of oral contraceptives for the wealthy is financial, while the cost of oral contraceptives for the poor is bodily invasion.

The rationale of *Harris* is that the government's regulation (limiting the range of medical services it would fund) was not a "deprivation" or "denial" because privacy and other fundamental rights are exclusively "negative" rights—i.e., the individual has a right to be left alone and not be "disturbed" by the government—and failure to fund abortions did not violate the negative right to privacy.[228] In contrast, the regulation requiring a pelvic exam violates the individual's negative right to bodily integrity.[229] The performance of an invasive pelvic exam literally involves disturbance of the individual and can hardly be described as the individual's being left alone. To receive federally funded family planning services, an abortion seeker has to *forego* an *exercise* of the right to an abortion. To receive the desired federally funded family planning service (i.e., hormonal contraception), the contraception seeker has to *undergo* a *violation* of the right to bodily privacy.

Harris and *Rust* indicate that it is permissible for Medicaid not to fund abortion because lack of funding leaves poor women with the same choices and no worse off than they would have been had Medicaid never existed.[230] The pelvic exam requirement, however, creates a new set of choices, potentially leaving women worse off than if Title X had never existed.[231] The existence of the Title X program subjects women to potential pressure from partners or family members to undergo the exams in order to save the costs of private physicians; forces women who cannot afford to visit private providers to make decisions affirmatively to forego

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[225] *Id.*

[226] 432 U.S. 464 (1977) (upholding a state regulation granting Medicaid benefits for childbirth but denying such benefits for nontherapeutic abortions).

[227] 500 U.S. 173 (1991) (upholding an abortion gag rule imposed on recipients of federal health funds).

[228] *See* Appleton, *supra* note 116, at 18.

[229] This invasion of a negative right renders inapplicable Kathleen Sullivan's criticism of the coercion approach's articulation of a theoretical foundation for the unconstitutional conditions doctrine. Sullivan argues that it is unhelpful to identify coercion of beneficiaries as the harm of rights-pressuring conditions on government benefits in developing a theoretical foundation for solving unconstitutional conditions problems because to argue that conditions make recipients of the benefit worse off with respect to a benefit than they ought to be runs counter to the ground rules of a negative Constitution. Sullivan, *supra* note 138, at 1419–50.

[230] *Harris*, 448 U.S. at 316 (1980); *Rust*, 500 U.S. at 201–02.

[231] *See* Linda Maher, *Government Funding in Title X Projects: Circumscribing the Constitutional Rights of the Indigent:* Rust v. Sullivan, 29 CAL. W. L. REV. 143, 166 (1992) (characterizing the Title X program as a "government buy-back program" that attempts to purchase constitutional freedoms, under "the guise of a desperately needed health care program for poor Americans").

their constitutional rights, choosing between either long-term control over their futures or exercise of their rights to bodily integrity; and likely results in most women submitting to potentially emotionally traumatic bodily invasion,[232] as most women probably deem temporary violation of their constitutional rights to be "the lesser of two evils" when compared to long-term deprivation of their constitutional rights. In short, poverty—not conditions on federal spending—precludes abortion seekers *from receiving* desired services from private providers. Here, while poverty will have the same result of precluding oral contraceptive seekers from receiving desired services from private providers, the condition on spending itself also creates the accompanying result of countless women *being subjected to* undesired, invasive exams.

While the abortion funding cases emphasize the significant leeway the government has in structuring its medical programs, the Supreme Court has indicated that a certain degree of coercion is unacceptable.[233] The Court has found it impermissible for the government to present a choice of only "the lesser of the two evils."[234] Choosing between bodily invasion and lack of effective control over one's reproductive life certainly qualifies as such a choice. Therefore, the pelvic exam requirement is unacceptably coercive[235] in a way in which abortion restrictions are not.

Analysis of the pelvic exam requirement further differs from the analysis in the abortion funding cases because constitutional caselaw does not protect abortion in the same way it does birth control.[236] In the case of abortion, the government has a powerful interest that weighs against women's rights to bodily integrity and reproductive control: potential fetal life.[237] In the case of contraception, the balance necessarily shifts in favor of women's rights with the elimination of the government's interest in fetal life. Because birth control access receives more constitutional protection than does abortion, the pelvic exam requirement is most certainly impermissible as it is unnecessary to protect women's

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[232] It is argued that the unconstitutional conditions doctrine "attempts to prevent hierarchy among classes that, without the government intervention, would make the *same* choice." Sullivan, *supra* note 138, at 1497. By this argument, the pelvic exam requirement is an impermissible condition because it results in poor women making different choices than they would make if wealthier.

[233] David S. Coale, Note, *Norplant Bonuses and the Unconstitutional Conditions Doctrine*, 71 TEX. L. REV. 189, 201 (1992) (citing Sherbert v. Verner, 374 U.S. 398, 404 (1963) (criticizing an effort to induce Sherbert to modify her religious beliefs); Speiser v. Randall, 357 U.S. 513, 519 (1958) (observing that denying a tax exemption for engaging in certain forms of speech will have an impermissible chilling effect on speech)).

[234] Union Pac. R.R. v. Pub. Serv. Comm'n, 248 U.S. 67, 70 (1918).

[235] Based on its coercive nature and its perpetuation of a medically unnecessary requirement, the pelvic exam requirement has also been argued to be unethical. Stewart et al., *supra* note 49, at 2236.

[236] *See* Planned Parenthood v. Casey, 505 U.S. 833, 851–59 (1992); *see also* Silverberg, *supra* note 115, at 1606.

[237] *E.g.*, Rust v. Sullivan, 500 U.S. 173 (1991); Harris v. McRae, 448 U.S. 297 (1980); Maher v. Roe, 432 U.S. 464 (1977).

health and is a substantial obstacle that deters many women from obtaining effective contraception.[238] The question then becomes: does the government's interest in preventing a few (if any) adverse effects of oral contraceptive use, where less intrusive means of preventing those effects are available, outweigh women's right to maintain bodily integrity and control their reproduction? The answer is clearly no.

Casey implicitly held that an abortion regulation would also be impermissible if it were so rigid that it would not allow for a physician to exercise medical judgment in waiving compliance with the regulation due to adverse effects on the mental or physical health of the woman.[239] In the hormonal contraceptive context, which receives more protection, the mandatory pelvic exam requirement precludes physician waiver even if medical judgment suggests the procedure may result in unwarranted harm to the woman's mental or physical health.

While other types of contraceptives are available without a pelvic exam, they are not comparable because they are less effective, less convenient, and not entirely within the woman's control.[240] Contraceptive method preference also implicates religious beliefs and prohibitions.[241] Supporting these arguments is the logic of *Planned Parenthood Federation of America v. Schweiker*,[242] which implicitly rejected a requirement for women either to pay the costs of the pill from private providers or to accept a less effective method of birth control. In *Schweiker*, the court determined that a parental notice restriction on adolescents' access to birth control was unjustifiably intrusive because it would deter adolescents from using Title X clinics, thus undermining the clinics' purpose of reducing the number of unintended births and pregnancies.[243] An even stronger argument exists for invalidating the pelvic exam requirement because the privacy rights of adult women weigh more heavily against

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[238] *See infra* Part VII.A.1.

[239] *Casey*, 505 U.S. at 883–84.

[240] "The availability of safe, effective and convenient methods of contraception is central to a woman's control over her life and her fertility." Anna Birenbaum, *Shielding the Masses: How Litigation Changed the Face of Birth Control*, 10 S. CAL REV. L. & WOMEN'S STUD. 411, 424 (2001); *see also infra* Part VII.B.

[241] State and federal cases interpreting the First Amendment Free Exercise Clause have recognized the importance of religious objections to some medicines and treatments. Coale, *supra* note 233, at 201 (citing JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW 1237 (4th ed. 1991) ("When the objection to medical treatment is based on religious principles . . . a serious free exercise clause problem is presented.")). While, in this case, oral contraceptives might be undesirable for those with religious concerns (most forms of the pill prevent implantation of the fertilized egg, which may constitute abortion from the perspective of those who believe life begins at fertilization), the extensive entanglement of religious beliefs with preferences about contraception makes governmental involvement in choice of contraceptive method a complicated, and oftentimes controversial, issue.

[242] 559 F. Supp. 658 (D.D.C. 1983).

[243] *Id.* at 663–65.

the government's interests than do those of adolescents.[244] A pelvic exam is more intrusive than parental notification, and the Title X goal of prohibiting unintended pregnancies and abortions is just as important for adult women as it is for adolescents.[245] Under the rationale of *Schweiker*, poor women who are often economically dependent upon male partners or parents should not have to seek permission from others (in the form of financial support to see a private provider) to obtain effective oral contraception.[246]

C. The Greater Power Does Not Include the Lesser Power

According to the unconstitutional conditions doctrine, "although [the] government may choose not to provide certain benefits altogether, it may not condition the conferral of a benefit, once provided, on a benefi-ciary's waiver of a constitutional right."[247] The conventional opposing argument is that because the government does not have to provide subsidized contraceptive services at all, it has the power to restrict those provisions in any manner it wants. However, that argument fails where the benefit being provided is itself a constitutional entitlement. In the abortion context, a woman has a right to choose abortion but no entitlement to the means to achieve it, "even where such aid may be necessary to secure life, liberty, or property interests of which the government itself may not deprive the individual."[248] In contrast, women have not merely a right to choose to use effective contraceptives[249] but a constitutional entitlement of access to them, free from unjustified governmental interference.[250] "[W]hat the government cannot restrict for all, it may not restrict for those over whom it has special leverage because of their dependency."[251]

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[244] The Constitution weighs adolescents' rights against those of both their parents and the power of the state, whereas an adult's rights are weighed only against the state's. Arons, *supra* note 60, at 1096 n.23 (citing Carey v. Population Servs. Int'l, 431 U.S. 678, 692 (1977) (holding that the power of the state to regulate minors is greater than its power to regulate adults)).

[245] Title X is intended to serve all age groups in need of family planning services. 42 U.S.C. § 300 (2003); Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, § 6(c), 84 Stat. 1506 (1970).

[246] *See* Planned Parenthood v. Casey, 505 U.S. 833, 887–88 (1992) (holding that women have the right to make reproductive decisions even without their partners' approval); Planned Parenthood v. Danforth, 428 U.S. 52 (1976) (invalidating portions of a Missouri statute that required a woman seeking an abortion to obtain spousal consent if married or parental consent if unmarried and under the age of eighteen).

[247] Sunstein, *Unconstitutional Conditions Doctrine*, *supra* note 126, at 593 n.2 (citing LAURENCE TRIBE, AMERICAN CONSTITUTIONAL LAW § 10-8, at 681 & n.29 (2d ed. 1988)).

[248] DeShaney v. Winnebago, 489 U.S. 189, 196 (1989) (referring to Harris v. McRae, 448 U.S. 297 (1980)).

[249] Griswold v. Connecticut, 381 U.S. 479 (1965).

[250] Eisenstadt v. Baird, 405 U.S. 438, 453 (1972); *see also* Planned Parenthood v. Casey, 505 U.S. 833, 851–53 (1992) (affirming the right's continued existence).

[251] Sullivan, *supra* note 138, at 1499.

The existence of Title X family planning clinics is itself testimony to the government's recognition that many women would not have access to effective contraception without such clinics.[252] Because this right of access exists and the government has acknowledged a duty to provide access to effective contraception for the poor,[253] it does not have the power to refuse to fulfill this duty.[254] Moreover, although the government need not provide any access to contraception, the pelvic exam requirement still violates the fundamental right to be free from unjustified governmental interference in existing access to contraception[255] because the pelvic exam requirement's irrational and discriminatory nature makes it unjustifiable under any level of review.[256]

Even if a greater power includes any lesser power where both serve the *same* purpose,[257] the greater power to provide Title X family planning services does not include the lesser power to restrict access to oral contraceptives with irrelevant exams in order to protect women's health. The purpose of the greater power of establishing Title X family planning clinics is to reduce the number and adverse consequences of unintended pregnancies[258] and allow women to lead independent lives.[259] Rather than fully serving the purposes of Title X, the pelvic exam requirement actually defeats the Title X purposes of reducing the consequences of unintended

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[252] *See* 136 CONG. REC. S13,680 (daily ed. Sept. 25, 1990) (statement of Sen. Packwood) (acknowledging that Title X is the only source of contraceptives for many women); *id.* at S13,685 (statement of Sen. Adams) (acknowledging that 4.1 million women rely on Title X for contraceptive services); ALAN GUTTMACHER INST., FULFILLING THE PROMISE, *supra* note 8, at 6 (stating that Title X's "enactment sprang from a fundamental recognition that absent government support, only women who could afford a visit to a private physician and the method the physician prescribed would benefit from the new era of modern contraception"), *available at* http://www.guttmacher.org/pubs/fulfill.pdf.

[253] *See supra* note 1; HHS Proposed Rules for National Guidelines for Health Planning, 45 Fed. Reg. 78,552 (Nov. 25, 1980) [hereinafter HHS Proposed Rules] (acknowledging that in order for poor individuals to be independent, and to protect them from social, economic, and psychological health costs, public family planning services are necessary).

[254] *See* HHS, Unified Agenda, Statement of Regulatory and Deregulatory Priorities, 62 Fed. Reg. 57,043, 57,043 (1997) [hereinafter Unified Agenda] (stating that "[t]he Department of Health and Human Services (HHS) is statutorily obligated to protect and promote the health and the social and economic well-being of all Americans, and, in particular, of those least able to help themselves— . . . the disadvantaged—by helping them and their families develop and maintain healthy, productive, and independent lives").

[255] As in *Goldberg v. Kelly*, 397 U.S. 254 (1970), federal law (rather than the Constitution) has established the affirmative entitlement to provision of contraceptives here, so Title X recipients have a property right in this welfare benefit which permits them to expect continued receipt of the benefits unless the government provides notice of and a hearing about an intent to discontinue the benefits.

[256] *See supra* Parts III.B–C and IV.C.

[257] *See* Sullivan, *supra* note 138, at 1460.

[258] This is true particularly among those at high risk for an unintended pregnancy (*e.g.*, poor and minority women). HHS Proposed Rules, *supra* note 253, at 78,564.

[259] Unified Agenda, *supra* note 254, at 57,043. HHS also acknowledges that in order for individuals to be independent, public family planning services are necessary. HHS Proposed Rules, *supra* note 253, at 78,564.

pregnancies and fostering women's independence.[260] Thus even were the government to have the power of not subsidizing contraceptives, this greater power would not include the lesser power to restrict access to subsidized contraceptives for only some recipients.

D. The Pelvic Exam Constitutes a Penalty Instead of a Mere Lack of Subsidy

The pelvic exam requirement amounts to an impermissible penalty on the exercise of the constitutional right of access to effective contraception. The traditional counterargument to this proposition is that the government is not penalizing the exercise of a right; rather, it is merely not providing a subsidy. However, this argument carries less weight when both the right being exercised and the subject of the subsidy itself are constitutional entitlements. Unlike the abortion context, the government has acknowledged a duty to provide poor women with the effective contraception to which they are constitutionally entitled.[261] The argument that it may refuse to subsidize oral contraceptives for those who decline a pelvic exam therefore fails. Wealthy women can exercise their constitutional right to contraceptive access without a pelvic exam. Poor women are "charged" a pelvic exam to exercise their right of access. The pelvic exam is therefore a penalty on women who cannot afford to visit a private practitioner.

Additionally, a condition on the exercise of a constitutional right constitutes a penalty if the condition is unrelated to the benefit.[262] In the abortion funding cases, the Supreme Court held that the lack of funding for abortions with public medical insurance was merely a nonsubsidy.[263] However, it conceded that the government's withdrawal of general welfare benefits[264] or all Medicaid benefits[265] from an otherwise needy woman for having an abortion would be a penalty due to the lack of germaneness of the condition to these benefits. Similarly, the pelvic exam's lack of germaneness to oral contraceptive prescription[266] renders the exam condition a penalty on the exercise of a constitutional right. In sum, the pelvic exam requirement is unconstitutional because it is impermissibly coercive to require the forfeiture of bodily privacy rights in exchange for

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[260] *See infra* Parts VII.A.2 (increase in unwanted pregnancies and abortions) and VII.C (decreased autonomy of women).

[261] *See supra* note 32.

[262] *See* Sullivan, *supra* note 138, at 1464.

[263] Maher v. Roe, 432 U.S. 464, 474 n.8 (1977); *see also* Sullivan, *supra* note 138, at 1464.

[264] *Maher*, 432 U.S. at 474 n.8; *see also* Sullivan, *supra* note 138, at 1464.

[265] Harris v. McRae, 448 U.S. 297, 317 n.19 (1980); *see also* Sullivan, *supra* note 138, at 1464.

[266] *See supra* Parts III.B.1–2.

the exercise of the right to reproductive autonomy and access to effective contraception.[267]

VI. Impermissible Statutory Construction

Even if the pelvic exam requirement is constitutional, it is nonetheless impermissible under administrative law. Because Congress explicitly delegated authority to HHS to create regulations under Title X,[268] the pelvic exam requirement is entitled to great deference by a reviewing court.[269] In deciding the legality of an agency's interpretation of statutory instructions, a court must first decide whether the legislature has directly addressed "the precise question at issue."[270] If, as here, it has not, the court must determine whether the agency's interpretation of the statute is acceptable.[271] Unless the regulation is arbitrary, capricious, or manifestly contrary to the statute, it will be upheld.[272] However, because the pelvic exam requirement is arbitrary and capricious and its effect is manifestly contrary to HHS's statutory instructions, administrative law requires that it be invalidated.

A. Legislative Intent of Title X Provisions

The statute delegating authority to HHS reads:

> The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services . . . .[273]

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[267] *See also* Maher, *supra* note 231, at 167 (arguing that if an American can ever bargain away his or her constitutional rights, this should never transpire between the government and the poor because the uneven bargaining power alone would invalidate any such contract).

[268] 42 U.S.C. § 300a-4 (2000) ("Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate.").

[269] Chevron, Inc. v. Natural Res. Def. Council, 467 U.S. 837, 845 (1984); United States v. Mead Corp., 533 U.S. 218, 229 (2001).

[270] *Chevron*, 467 U.S. at 842.

[271] *Id.* at 842–43. The pelvic exam requirement is maintained by "interpretive guidance" from OPA, rather than a legislative rule by HHS, and it "did not require clearance by other agencies within the government or publication in the Federal Register because it does not establish new policy." Nat'l Cervical Cancer Coalition, *supra* note 80, *available at* http://www.nccc-online.org/fppaps_12.asp. Therefore, a court would probably review the requirement with lesser deference, as in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

[272] *Chevron*, 467 U.S. at 844.

[273] 42 U.S.C. § 300 (2003).

> Grants and contracts made under this title . . . shall be made in accordance with such regulations as the Secretary may promulgate.[274]

The statute itself does not address the specific issue of the necessity of a pelvic exam prior to dispensing oral contraceptives but grants explicit authority to HHS to create regulations. Therefore, a reviewing court will defer to the HHS decision to require pelvic exams of women seeking oral contraceptives unless the regulation can be shown to be arbitrary, capricious, or manifestly contrary to the statute.

B. Impermissible Construction of Title X Provisions

The requirement for a pelvic exam prior to dispensing oral contraceptives in Title X programs was initially articulated in 1976 in the program guidelines developed by ACOG for project grants for family planning services.[275] Today, the requirement is maintained under a policy of OPA to follow FDA-required drug label prescribing information for contraceptives dispensed through its programs, and an interpretation by OPA that language in FDA package insert labeling *requires* women to receive pelvic exams prior to beginning oral contraceptives and annually thereafter.[276] As an example of such language, one FDA insert specifies that "[a] complete medical history and physical examination *should* be taken prior to the initiation or reinstitution of oral contraceptives and at least annually during use of oral contraceptives. These physical examinations should include special reference to . . . pelvic organs, including cervical cytology."[277]

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[274] 42 U.S.C. § 300a-4 (2000).

[275] PUB. HEALTH SERV., U.S. DEP'T OF PUB. HEALTH, EDUC., AND WELFARE, PROGRAM GUIDELINES FOR PROJECT GRANTS FOR FAMILY PLANNING SERVICES UNDER SECTION 1001, PUBLIC HEALTH SERVICES ACT 11-13 (1976). The requirement for a pelvic exam prior to and annually after dispensing oral contraceptives under the Title XIX Medicaid, Title V MCH Block Grant, and Title XX Block Grant programs was articulated by the U.S. Public Health Service in 1967. PROGRAM AREA COMM. ON POPULATION & PUB. HEALTH, FAMILY PLANNING: A GUIDE FOR STATE AND LOCAL AGENCIES 66 (1968) (citing Pub. Health Servs., Dep't of Health, Educ., and Welfare, Division of Direct Health Services Circular Memo No. 67-14 (1967)).

[276] OFF. OF POPULATION AFFAIRS, *supra* note 108, § 8.3; *see* Memorandum from Jerry Bennett to Regional Health Administrators of Title X programs, *supra* note 80 (discussing the continued existence of the pelvic exam requirement and stating that "Title X has traditionally taken the position that grantees should conform to current FDA policy as expressed in its labeling standards for contraception. OPA continues to be of the view that this policy is appropriate . . . ."), *available at* http://opa.osophs.dhhs.gov/titlex/pis/opa93-1.pdf; Nat'l Cervical Cancer Coalition, *supra* note 80, *available at* http://www.nccc-online.org/fppaps_12.asp.

[277] FDA package insert labeling for oral contraceptives, *cited in* DICKEY, *supra* note 69 at 184 (emphasis added). Another FDA label asserts that "[i]t is good medical practice for women using [hormonal contraception], as for all women, to have an annual medical evaluation including physical examination . . . [which] *should* include special reference to . . .

The text of the statute, the legislative history surrounding it, and the overall purpose of Title X render the pelvic exam requirement impermissible because the decisions to implement and maintain the requirement are arbitrary and capricious, and its effect is directly contrary to its purpose. By eliminating oral contraceptives from the family planning options available to women who do not want to undergo a pelvic exam, the requirement a reduces the "broad range of *acceptable* . . . family planning methods offer[ed]" to women and diminishes the "broad range of . . . *effective* family planning methods offer[ed]" to women[278]—results directly contrary to the language of the statute.

In contrast to other public health laws, which are intended to provide a broad range of general health care services,[279] the exclusive purpose of Title X is to provide family planning services.[280] Within this narrowly defined objective, the primary goals are prevention of unintended pregnancy and improvement of maternal health.[281] HHS's construction of the statute to require pelvic exams is arbitrary and capricious because women do not need a pelvic exams to serve Congress's goal of preventing unintended pregnancy or improving maternal health.[282] In fact, the requirement is manifestly contrary to congressional intent in enacting Title X because its deterrent effect results in increases in unwanted pregnancies[283] and greater risks to maternal health.[284] Furthermore, in the absence of any statutory instruction to consider factors which might support the requirement of a pelvic exam on other grounds, the fact that the requirement serves no purpose that is relevant to oral contraceptive use[285] renders it arbitrary and capricious.[286]

The arbitrariness of the requirement is further apparent in its inconsistency with OPA's own policy of following FDA labeling guidance. OPA's interpretation of "should" to mean "must" is arbitrary and capri-

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pelvic organs and vagina (including cervical cytology)." FDA package insert labeling for NuvaRing (emphasis added), *available at* http://www.epigee.org/guide/inserts/nuvaring.pdf (last visited Feb. 1, 2004).

[278] 42 U.S.C. § 300 (2003) (emphasis added).

[279] *E.g.*, Medicaid, Title XIX of the Social Security Act, 42 U.S.C. § 1396 (2000); MCH Block Grant program, Title V of the Social Security Act, 42 U.S.C. §§ 701–709 (2000).

[280] 136 CONG. REC. S13,685 (daily ed. Sept. 25, 1990) (statement of Sen. Adams); ALAN GUTTMACHER INST., FULFILLING THE PROMISE, *supra* note 8, at 6, 22 (citing Pub. L. No. 91-572), *available at* http://www.guttmacher.org/pubs/fulfill.pdf; Dailard, *supra* note 7, at 6.

[281] 136 CONG. REC. S13,676 (daily ed. Sept. 25, 1990) (statement of Sen. Kennedy that "[t]he purpose of [T]itle X is to provide services and information to reduce the incidence of unintended pregnancy, to improve maternal health, and to reduce the need for abortion").

[282] *See supra* Parts III.B.1 and III.B.2.

[283] *See infra* Part VII.A.2.

[284] *See supra* Part III.B.1.c.

[285] *See supra* Part III.B.1.

[286] SEC v. Chenery Corp., 318 U.S. 80, 94–95 (1943) (indicating that an agency must be able to explain why it has chosen to implement a regulation).

cious because there is no basis for equating the two. "Should" is understood in everyday parlance to indicate that something is beneficial or preferable, whereas "must" is understood to indicate that something is mandatory and nonnegotiable. If OPA had accurately followed FDA labeling guidance, publicly funded clinics would have a policy urging women seeking oral contraceptives to get pelvic exams instead of a policy requiring them as an absolute prerequisite. Because HHS's construction of its statutory instructions for administering Title X programs is arbitrary, capricious, and manifestly contrary to Congress's intent, the requirement should be invalidated.

VII. Public Policy Arguments for Eliminating Mandatory Pelvic Exams

Even if a court upheld the pelvic exam requirement on legal grounds, it should be eliminated because it constitutes bad public policy. A 1993 task force that reviewed Title X guidelines recommended removing the pelvic exam requirement and leaving it to clinician discretion to determine whether or not such an exam is necessary prior to dispensing hormonal contraception.[287] This recommendation is good public policy because it encourages use of contraception, helps to weaken gender stereotypes, is consistent with related bodies of law, and is supported by a cost-benefit analysis.

A. Encouragement of Contraceptive Use

Public policy and the legislation and regulations that implement it should encourage the use of contraceptives. Control of fertility provided by highly effective hormonal contraception allows women and couples to have children when they are best prepared financially and socially for parenting and its attendant responsibilities, resulting in fewer unanticipated costs to individuals. It also prevents women and couples from having to make difficult decisions about whether to have abortions and protects society from bearing the abortion- and pregnancy-related costs of women who are financially unprepared for unplanned pregnancies. The pelvic exam requirement's deterrent effect creates increased costs to society and individuals.

1. Deterrent Effect

Mandated pelvic exams deter women from obtaining hormonal contraceptives.[288] Roughly 15% of women with a high school diploma or

[287] Harper et al., *supra* note 74, at 13.
[288] Humphrey Taylor, *Survey of and Barriers to Pill Use*, *in* The Pill: From Prescrip-

lower education level and 11% of women with at least some college education cite the pelvic exam as a factor in deciding whether to use oral contraceptives.[289] In a program providing low income women hormonal contraceptices, 76% of the women said it was important to be able to obtain birth control pills or injections without a pelvic exam, 86% responded favorably to the idea, 75% associated pelvic exams with embarrassment and fear, and 31% reported that these feelings had prevented them from obtaining a pelvic exam at some point.[290] In another study, 16.7% of women said they would be more likely to use birth control pills if they did not first have to get a pelvic exam.[291] A survey conducted in three foreign countries showed that respondents in all countries believed a "user-friendly" process for accessing contraception "should not require a pelvic examination."[292] Although only 56% of clinics dispensing oral contraceptives, 42% of clinics offering injectable contraceptives, and 23% of clinics providing the implant allow delayed pelvic exams, 69% of all women going to clinics for contraceptives choose those clinics, further suggesting women's aversion to undergoing such an exam.[293]

The pelvic exam requirement is also unwise public policy because it reinforces the common but incorrect perception that hormonal methods of birth control are dangerous, deterring use of effective contraception.[294] An evaluation of California's First Stop program, which provided hormonal contraception to women without requiring them to undergo a pelvic exam, concluded that lack of a pelvic exam requirement improves the frequency of women utilizing reproductive health services.[295] The program also demonstrated that the provision of contraception without a pelvic exam resulted in a significant improvement in women's use of ef-

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TION TO OVER THE COUNTER, *supra* note 67, at 53, 67 tbl. 9; Best, *supra* note 73, *available at* http://www.reproline.jhu.edu/English/6read/6issues/6network/v21-3/nt2131.htm; MEAD, *supra* note 67, at 5 tbl. 1 (citing pelvic exams as unwarranted psychological barriers to oral contraceptives). Adolescents especially are deterred from obtaining contraception by fear of pelvic exams. *See* Stewart et al., *supra* note 49, at 2236 (stating that young women often forego medical care to receive contraception when they become sexually active due to anxiety about pelvic exams); Cromer & McCarthy, *supra* note 75, at 292 (citing ELISE F. JONES ET AL., TEENAGE PREGNANCY IN INDUSTRIALIZED COUNTRIES (1986)); Shafer, *supra* note 49, at 69; LAURIE SCHWAB ZABIN & SARAH C. HAYWARD, ADOLESCENT SEXUAL BEHAVIOR AND CHILDBEARING 67, 73 (1993) (reporting that for 24.8% of adolescents, fear of the examination is a factor in decisions to delay seeking family planning services); Am. Acad. of Pediatrics, Comm. on Adolescence, *supra* note 18, at 134.

[289] Taylor, *supra* note 288, at 67 tbl. 9.

[290] Harper et al., *supra* note 74, at 16.

[291] Sable et al., *supra* note 79, at 124. The percentage of women who hold this view is probably much higher, as the women surveyed were presumably disproportionately those who had decided to submit to the exam because they were already at the clinic to obtain contraceptives.

[292] Cromer & McCarthy, *supra* note 75, at 287.

[293] Finer et al., *supra* note 6, at 19.

[294] Stewart et al., *supra* note 49, at 2232.

[295] Harper et al., *supra* note 74, at 13.

fective contraceptive methods after their initial visit to the program: 38% adopted a more effective method than that used before their visits.[296]

2. Increase in Unwanted Pregnancies and Abortions

The deterrent effect of the pelvic exam requirement results in the use of either nonhormonal contraception or no contraception at all. Nonhormonal methods of contraception are both less effective[297] and less desirable for convenience[298] and enjoyment[299] reasons. The resultant decrease in use of effective contraception increases the number of unintended pregnancies and, thus, forces women and couples to confront difficult decisions about abortion that they would presumably prefer to avoid.[300] Currently, of women aged fifteen to forty-four, 28% have had at least one unintended birth and 30% have had at least one abortion.[301] Furthermore, 54% of unintended pregnancies end in abortion.[302] By eliminating the pelvic exam requirement and its accompanying hormonal contraceptive-deterrent effect, the number of unwanted pregnancies and abortions will decrease.

3. Increased Costs to Society

Unwanted pregnancies, whether ending in abortion or birth, create costs for individuals[303] and society. Currently, roughly half of all pregnancies in the United States are unintended, including 59% among women between twenty and twenty-four years of age and 78% among never-married women.[304] The unintended pregnancy rate is highest among young, low-

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[295] *Id.*

[297] *See supra* note 18.

[298] Nineteen percent of women report that condoms make sex less spontaneous. Sable et al., *supra* note 79, at 127.

[299] Thirteen percent of women assert that there is no point in getting condoms because men do not like to use them; 25% of women report that condoms make sex less pleasurable. *Id.*

[300] *See* 136 CONG. REC. S13,686 (daily ed. Sept. 25, 1990) (statement of Sen. Adams) (asserting that "it is one of the great tragedies of this country that we allow unintended pregnancies, to force very young women, often very poor young women, to a point where they have to make choices that they would not otherwise have to make").

[301] Stanley K. Henshaw, *Unintended Pregnancy in the United States*, FAM. PLAN. PERSP., Jan.-Feb. 1998, at 24, 24 (reporting 1994 data).

[302] *Id.*

[303] For example, unintended conception appears to be a risk factor for violence during pregnancy. Of the women who reported physical violence during pregnancy, almost 70% were women with unwanted or mistimed pregnancies. Additionally, although the direction of causation is unclear, 12% of accidentally pregnant women are abused, whereas only 3% of intentionally pregnant women are abused. Melissa Moore, *Reproductive Health and Intimate Partner Violence*, FAM. PLAN. PERSP., Nov.-Dec. 1999, at 302, 304 (citing J. A. Gazmarian et al., *The Relationship Between Pregnancy Intendedness and Physical Violence in Mothers of Newborns*, 85 OBSTETRICS & GYNECOLOGY 1031, 1031 (1995)).

[304] Sable et al., *supra* note 79, at 124 (citing Henshaw, *supra* note 301, at 26 tbl. 1).

income, minority women.[305] These are also the women most likely to have financial and social difficulty caring for an unanticipated child.[306] In spite of the inability to support a child and the life disruption that can be caused by an unplanned birth, about half of unintended pregnancies result in birth.[307] Publicly funded clinics are prohibited from providing abortion services,[308] and abortions are even more expensive than initiation of oral contraceptives through a private provider.[309] Thus, the economically disadvantaged woman who is denied effective contraception because she declines a pelvic exam and who then becomes pregnant but cannot afford an abortion is left with the far greater expenses of pregnancy and childrearing,[310] which she is also unable to meet. Consequently, these pregnancies result in increased costs to society because these women and their children require publicly funded services.[311]

The pelvic exam itself also increases costs to society. The intensive professional time and equipment necessary to perform the exam make it very expensive.[312] Public money is used (under Title X) to pay these costs. By eliminating the requirement, administrative costs would decrease, as would the costs of funding pregnancy, childbirth, and abortions for women

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[305] Henshaw, *supra* note 301, at 24.

[306] *Id.* at 29.

[307] *Id.*

[308] 42 U.S.C. § 300a-6 (2000).

[309] The cost of an abortion ranges between $250 and $1067, depending on the method used and gestational age. Planned Parenthood Fed'n of Am., *Ask the Experts*, *at* http://www.teenwire.com/ask/2002/as_20021108p465_abortion.asp (Nov. 8, 2002) (last visited Feb. 1, 2004); Planned Parenthood Fed'n of Am., *Fact Sheet: Abortion After the First Trimester* (June 2001) *at* http://www.plannedparenthood.org/library/facts/abotaft1st_010600.html (last visited Feb. 1, 2004). Initiation of oral contraceptives through a private provider costs $50–$125 for the visit and $20–$35 per month for the pill. Planned Parenthood Fed'n of Am., *You and the Pill*, *at* http://www.plannedparenthood.org/bc/you_and_pill.htm (last visited Feb. 1, 2004).

[310] The cost of pregnancy on average is $6,400 and the cost of childrearing is estimated to be $8,951 per year for lower-class families. *See* Women's Issues, *Unplanned Pregnancy—How Much Does It Cost?* (cost of pregnancy), *available at* http://www.womensissues.about.com/library/unplanned/blkeepcost.htm (last visited Feb. 1, 2004); Kindell, *supra* note 132, at 415 (cost of childrearing). This expense occurs in the form of both health risks and monetary costs. The risks in childbirth of permanent damage to health and to life itself are vastly greater than the risks of abortion (approximately seven times greater in childbirth than in first trimester abortion), and the health risks of both pregnancy and childbirth are exacerbated in an unwanted pregnancy. Law, *supra* note 60, at 1017 (citing Scot Lebolt et al., *Mortality from Abortion and Childbirth: Are the Statistics Biased?*, 248 JAMA 192 (1982); Cates, *Legal Abortion: The Public Health Record*, 215 SCI. 1586, 1587 (1982); Scot Lebolt et al., *Mortality from Abortion and Childbirth: Are the Populations Comparable?*, 248 JAMA 188 (1982)). Alternatively, a woman could give her unintended child up for adoption, but this still involves psychological costs. *See* Colker, *supra* note 211, at 352 (citing Steven McLaughlin et al., *Do Adolescents Who Relinquish Their Children Fare Better or Worse Than Those Who Raise Them?*, FAM. PLAN. PERSP., Jan.-Feb. 1998, at 25, 25).

[311] Gold, *supra* note 10, at 5; *see also* Henshaw, *supra* note 301, at 29.

[312] Shafer, *supra* note 49, at 69.

who would otherwise become pregnant through lack of access to effective contraception and then require financial assistance.

B. Perpetuation of Gender Stereotypes

Good public policy seeks to eliminate or weaken gender stereotypes that perpetuate patriarchal gender hierarchy.[313] The pelvic exam requirement maintains gender stereotypes because it decreases the autonomy of women, derails education and career goals, and forces undesired maternal roles and responsibilities upon women.

1. Decreased Autonomy of Women

The pelvic exam requirement perpetuates stereotypes of women as submissive and dependent because it decreases their autonomy over their fertility, causing them to lose physical, social, and financial independence and power.[314] The denial of hormonal contraception upon refusal of a pelvic exam leaves women in the uncomfortably vulnerable position of relying upon birth control methods which are at least partly within their partners' control.[315]

In situations of forced sex, women are particularly vulnerable to an undesired pregnancy because their aggressors are unlikely to use contraception.[316] Abused women in general are less likely than nonabused women to report having used condoms during their last sexual encounter,[317] and studies of young women indicate that the degree of "wantedness" of their first voluntary intercourse is positively correlated with the probability of contraceptive use.[318] Given the frequency of unwilling sex,[319] particularly

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[313] *See* United States v. Virginia, 518 U.S. 515, 534 (1996) (discussing the impermissibility of sex classifications that perpetuate gender role stereotypes).

[314] HHS's Statement of Regulatory and Deregulatory Policies explicitly states in its "overall priorities" that it is statutorily obligated to help disadvantaged Americans maintain independence. 62 Fed. Reg. 57,043, 57,043 (Oct. 29, 1997).

[315] All nonhormonal contraceptive methods but the IUD require at least the patience—if not the assistance—of the male partner. *Cf.* Sable et al., *supra* note 79, at 127 tbl. 2 (citing the need to trust one's partner as a barrier to condom use by thirty-five percent of women surveyed).

[316] Joyce Abma et al., *Young Women's Degree of Control over First Intercourse: An Exploratory Analysis*, FAM. PLAN. PERSP., Jan.-Feb. 1998, at 12, 12.

[317] Moore, *supra* note 303, at 304 (citing J. Greenberg, Childhood Sexual Abuse and Risk of STDs in Women: Intervention Strategies (paper presented at the National Conference on Violence and Reproductive Health, Atlanta, GA, June 1999)).

[318] Abma et al., *supra* note 316, at 15–16.

[319] Fourteen percent of women report having had forced sexual contact with someone their own age. Iviva Olenick, *Women Exposed to Childhood Abuse Have Elevated Odds of Unintended Pregnancy as Adults*, FAM. PLAN. PERSP., Jan.-Feb. 2000, at 47, 47. Presumably this percentage increases when forced contact with someone of a different age group is included. A survey of women seeking pregnancy tests revealed 2.3% were seeking them as a result of forced sex. Sable et al., *supra* note 79, at 127 tbl. 2.

among younger women, this problem is substantial.[320] Victims of intimate partner violence may be or may perceive themselves to be rendered powerless by abuse, which could make it difficult to negotiate condom use with their partners.[321] Research suggests that abuse affects women's ability or motivation to prevent an unintended first pregnancy.[322] The cycle of physical vulnerability is then perpetuated because women who do become pregnant are then at a greater risk of experiencing domestic violence.[323] Furthermore, women who are sexual abuse victims may be particularly averse to an intrusive pelvic exam.[324]

Even in situations of consensual sex, women often fail in their efforts to negotiate use of contraception with their partners,[325] oftentimes "due to economic dependence, social norms, and fear of physical violence."[326] Moreover, even when both sexes understand the strengths and

[320] Because recipients of publicly funded family planning services tend to be younger women, 136 CONG. REC. S13,685 (daily ed. Sept. 25, 1990) (statement of Sen. Adams), the especially high rate of unwilling sex among this age group underscores the need for provision of controllable and reliable hormonal contraception at publicly funded clinics. Twenty-six percent of teenage girls cite being "force[d] . . . against their will" as the reason they "often" have sex; sixty-one percent of teenage girls report that pressure from a boyfriend is the reason they "often" have sex. The Kaiser Fam. Found., Survey on *Teens and Sex: What They Say Teens Today Need To Know, and Who They Listen to*, *available at* http://www.kff.org/youthhisvstds/1159-teench.cfm (last visited Feb. 1, 2004).

[321] Moore, *supra* note 303, at 304 (citing Sandra L. Martin, *Women in Prenatal Care/Substance Abuse Treatment Program: Links Between Domestic Violence and Mental Health*, 2 MATERNAL & CHILD HEALTH 85, 85–94 (1998)).

[322] Olenick, *supra* note 319, at 48. A strong correlation exists between childhood sexual abuse and adolescent pregnancy: between fifty and sixty-five percent of teenage mothers have been victims of childhood sexual abuse or assault. Arons, *supra* note 60, at 1118 n.181.

[323] AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES, *supra* note 55, at 88; *see also* Planned Parenthood of S.E. Pennsylvania v. Casey, 505 U.S. 833, 889 (1992) (citing the district court's finding that "[m]ere notification of pregnancy is frequently a flashpoint for battering and violence within the family. The number of battering incidents is high during the pregnancy and often the worst abuse can be associated with pregnancy.").

[324] Women who are the victims of sexual abuse demonstrate a heightened aversion to bodily intrusion. *See* Jennifer Burian, *Helping Survivors of Sexual Abuse Through Labor*, (explaining how, for victims of sexual abuse, gynecological clinic visits so resemble their abuse that they are often virtually intolerable, and quoting one victim as saying, "I have to be half dead before I go . . . a yearly pelvic is about once every three to four years") *at* http://www.gentlebirth.org/archives/abuselbr.html (last visited Feb. 1, 2004); *see also* AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES, *supra* note 55, at 142 (acknowledging the need for sensitivity in performing exams on women who have been the victims of sexual assault, due to their vulnerability).

[325] Sable et al., *supra* note 79, at 127 (finding that thirteen percent of women report that their partners will not use condoms); *see* ALAN GUTTMACHER INST., FULFILLING THE PROMISE, *supra* note 8, at 37, (citing that a barrier to successful contraception is male partners' lack of support for birth control choices) *available at* http://www.guttmacher.org/pubs/fulfill.pdf. This is especially problematic for women within lower socioeconomic groups, as many men in these groups view pregnancy as enhancing their masculinity. Renata Forste & Julie Morgan, *How Relationships of U.S. Men Affect Contraceptive Use and Efforts to Prevent Sexually Transmitted Diseases*, FAM. PLAN. PERSP., Mar.-Apr. 1998, at 56, 57.

[326] Sable et al., *supra* note 79, at 129 (citing D. Worth, *Sexual Decision-Making and AIDS: Why Condom Promotion Among Vulnerable Women is Likely to Fail*, 20 STUD. IN FAM. PLAN. 297, 297–307 (1989)).

weaknesses of contraceptive alternatives,[327] men and women have different priorities when choosing contraceptive methods,[328] and each sex perceives greater efficacy in the method more within his or her respective control.[329] Research shows that men's involvement in decisions about contraception, sex, and childbearing strongly affects contraceptive behavior and that use of male-controlled methods continues to increase, despite the fact that female-controlled methods are generally more effective.[330] Female power in intimate relationships is positively correlated with use of contraception, while decreased female power is associated with decreased contraceptive use.[331]

Even when their partners do use contraception, women may still feel vulnerable without access to hormonal contraception because nonhormonal methods are less effective.[332] When alcohol use, spontaneity, or other factors result in voluntary (though perhaps impulsive or regrettable) unprotected sex, women are left with the possibility of pregnancy which would have been prevented by hormonal contraception.[333]

Unintended pregnancies resulting from women's lack of control over fertility further decrease women's autonomy because unplanned pregnancies increase poverty levels of individual women.[334] This leads to financial dependence upon male partners, family members, and/or public welfare. This loss of autonomy can be easily alleviated by the use of hormonal contraceptive methods because their reliability and female-based control allow women to prevent almost all unintended pregnancies.[335]

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[327] William R. Grady et al., *Contraceptive Characteristics: The Perceptions and Priorities of Men and Women*, FAM. PLAN. PERSP., July-Aug. 1999, at 168, 174.

[328] Men value protection against STDs more than women do, while women view prevention of pregnancy as the single most important factor in choice of contraceptive method. *Id.* at 171.

[329] *See id.* at 172 (finding that seventy-five percent of women and sixty-seven percent of men believed the pill to be "very good" at pregnancy prevention, while twenty-nine percent of women and forty-six percent of men believed condoms to be "very good" at pregnancy prevention).

[330] Grady et al., *supra* note 327, at 168.

[331] Abma et al., *supra* note 316, at 17 (citing S.R. Jorgensen et al., *Dyadic and Social Network Influences on Adolescent Exposure to Pregnancy Risk*, 42 J. MARRIAGE & FAM. 141 (1980)).

[332] While condoms are the most common and the most effective form of nonhormonal contraception used, thirty-eight percent of women feel they "aren't a good method because they can break." Sable et al., *supra* note 79, at 127; *see also* MEAD, *supra* note 67, at 4 (emphasizing the psychological benefits for women on the pill who know they are protected by an extremely effective form of birth control).

[333] Sable et al., *supra* note 79, at 127 (finding that ten percent of women seeking pregnancy tests reported contraception was not used because the sex was spontaneous).

[334] Gold, *supra* note 10, at 5, *available at* http://www.guttmacher.org/journals/tgr_archive.html. *See generally* HAROLD L. SHEPPARD, EFFECTS OF FAMILY PLANNING ON POVERTY IN THE UNITED STATES (W. E. Upjohn Inst. for Employment Research ed., 1967).

[335] *See* Erickson v. Bartell Drug Co., 141 F. Supp. 2d 1266, 1273 (W.D. Wash. 2001) (noting that the availability of a reliable way to prevent unintended pregnancies would go a long way toward ameliorating the costs and health consequences of the unwanted pregnancy for the mother, the child, and society as a whole, including economic and social

In short, access to hormonal contraception allows women to be assured of almost complete protection from pregnancy at all times, even if freedom from unwanted sexual intercourse and adequate bargaining power with consensual partners cannot be guaranteed. This control over fertility leads to autonomy in other aspects of life, including financial and social independence.[336] Public policy should encourage increased autonomy of women not just for ideological reasons but because it benefits individuals and society.[337] The pelvic exam requirement results in decreased female autonomy and should therefore be eliminated.

2. Derailment of Education and Career Goals

The increase in unwanted pregnancies that results from the contraceptive-deterrent effect of the pelvic exam requirement perpetuates stereotypes of women as uneducated and financially dependent on men.[338] Unintended childbearing reduces women's ability to complete their educations and participate in the work force.[339] Women who find themselves pregnant are often forced to drop out of school, limiting their career options and earning potential.[340] Women already in the work force may be compelled to change jobs or stop working in order to accommodate the responsibilities of parenthood. For mothers who do continue on their intended trajectory, career goals may be thwarted because of many employers' attitudes toward working mothers, which affect hiring, promotion, and responsibility-allocation decisions.[341]

It is only worthwhile for women to make career investments if the chance of becoming unintentionally pregnant can be essentially eliminated.[342] Control over fertility allows women to achieve education and

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consequences which prevent women from participating fully and equally in the marketplace of ideas).

[335] *See* 136 CONG. REC. S13,685 (daily ed. Sept. 25, 1990) (statement of Sen. Adams) (acknowledging that control over one's life through the ability to make responsible plans about having children is "the beginning of success").

[337] Autonomy over life and body has been found to account for increased use of effective contraceptive methods in women, reducing the costs to society of unwanted pregnancies and abortions. *See* Sable et al., *supra* note 79, at 130.

[338] Women who do not work outside the home have been characterized as "one man away from disaster." KRISTIN LUKER, ABORTION AND THE POLITICS OF MOTHERHOOD 176 (1984).

[339] Gold, *supra* note 10, at 5, *available at* http://www.guttmacher.org/journals/tgr_archive.html.

[340] *See* 136 CONG. REC. S13,677 (daily ed. Sept. 25, 1990) (statement of Sen. Kennedy); *id.* at S13,684 (statement of Sen. Jeffords).

[341] This type of impermissible discrimination is difficult to prove. *See* Daniel R. Ortiz, *The Myth of Intent in Equal Protection*, 41 STAN. L. REV. 1105 (1989); Law, *supra* note 60, at 1006. A woman's only true "remedy" for the damage she may suffer is the ability to prevent herself from ending up in such a vulnerable position.

[342] CLAUDIA GOLDEN & LAWRENCE F. KATZ, THE POWER OF THE PILL: ORAL CONTRACEPTIVES AND WOMEN'S CAREER AND MARRIAGE DECISIONS 2 (Nat'l Bureau of Econ. Research, Working Paper No. 7527, 2000).

career goals and their attendant social and financial independence.[343] The pelvic exam requirement is an unwarranted obstacle to fertility control that results in derailed goals for women and is, therefore, bad public policy.

3. Forced Maternal Roles and Responsibilities

The increase in unintended pregnancies resulting from the pelvic exam requirement perpetuates gender stereotypes of women as "naturally" maternal because it leads to forced maternal roles and responsibilities for those women whose beliefs, values, or decisions preclude abortion and weigh against adoption. For many women, the role of motherhood may be uncomfortable or simply undesired.[344] The responsibilities of motherhood are far from insignificant.[345] To impose these responsibilities upon women simply because they are averse to pelvic exams is unjustifi-able: it robs women of autonomy and perpetuates the notion that womanhood equals maternity.[346] The pelvic exam's effect of strengthening gender role stereotypes renders it a bad public policy choice.

C. Consistency with Related Laws

Good public policy maximizes consistency among laws to strengthen the legal system. The pelvic exam requirement, however, creates unjustified inconsistencies with related areas of law, including voluntariness in Title X programs and medical decisions.

Title X requires that services be voluntary.[347] Under this requirement, a woman may not be pressured or coerced to accept a particular contraceptive method.[348] Rather, there must be a real choice of contraceptives made available under Title X, allowing women to exercise reproductive autonomy.[349] For some, the pelvic exam removes this choice and coerces women into foregoing effective contraceptive methods. As a result, the goal of the program—to "assist in making comprehensive, voluntary family plan-

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[343] One of the specifically articulated goals of Title X family planning clinics is to enable women to complete their educations by avoiding unwanted pregnancies. 136 CONG. REC. S13,677 (daily ed. Sept. 25, 1990) (statement of Sen. Kennedy).

[344] *See* Erickson v. Bartell Drug Co., 141 F. Supp. 2d 1266, 1273 (W.D. Wash. 2001) (noting that "[b]eing pregnant . . . is not a state that is desired by all women or at all points in a woman's life").

[345] *See* BABER & ALLEN, *supra* note 142, at 102 (arguing that "the responsibility of bearing and caring for children has limited women's autonomy and ability to participate in activities that enhance their personal development and their social and economic status").

[345] *See generally* MARDY S. IRELAND, RECONCEIVING WOMEN: SEPARATING MOTHERHOOD FROM FEMALE IDENTITY (1993) (discussing the existence of an implicit assumption that motherhood is intrinsic to adult female identity).

[347] 42 C.F.R. § 59.5(a)(2) (2002).

[348] OFF. OF POPULATION AFFAIRS, *supra* note 108, § 5.1; *see also* Dailard, *supra* note 7, at 8.

[349] Dailard, *supra* note 7, at 8, *available at* http://www.guttmacher.org/journals/tgr_archive.html.

ning services readily available to all persons desiring such services"[350]—is not met: elimination of hormonal methods of contraception from women's options results in neither comprehensive service availability nor voluntary method choice.

Title X provisions also specify that acceptance of family planning services must not be a "prerequisite to eligibility for or receipt of any other service or assistance from or participation in any other programs" of the clinic.[351] By requiring the reproductive health service of a pelvic exam as a prerequisite to the separate service of provision of contraceptives, the voluntariness mandate of Title X is threatened. Accessibility to family planning services is also required under Title X.[352] As the pelvic exam requirement is a barrier to program recipients' equal access to reliable contraception,[353] it is inconsistent with HHS's own rules surrounding Title X.

As in other areas of medical care, women should have the right to make their own medical decisions concerning contraception.[354] Title X regulations specify:

> The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding their reproductive health and the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety about reproductive issues and to enhance their capacity to arrive at a decision that reflects their considered self-interest . . . .[355]

This language indicates an intent for the client to make her own health care decisions—specifically in choosing a method of contraception—in light of the risks and benefits surrounding each option. The role of the counselor is limited to providing the information necessary for the patient to make a decision; it does not include the authority to make deci-

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[350] Family Planning Services and Population Research Act of 1970, Pub. L. No. 91-572, § 6(c), 84 Stat. 1506 (1970).

[351] 42 U.S.C. § 300a-5 (2000).

[352] Title X program guidelines state that "[f]amily planning programs should, whenever possible, provide or coordinate access to services . . . ." OFF. OF POPULATION AFFAIRS, *supra* note 108, § 9.5.

[353] *See supra* Part IV.

[354] *See* Stewart et al., *supra* note 49, at 2235 (arguing that it is unethical to withhold hormonal contraception from women who decline a pelvic exam because they should have the right to make their own informed decisions about care, and stating that "[i]n other areas of medical care, [restricting patients' ability to make medical decisions] would not be perceived as appropriate"); Law, *supra* note 60, at 1020 (arguing that leaving the decision about abortion to the medical judgment of the pregnant woman's physician gives doctors undue power).

[355] OFF. OF POPULATION AFFAIRS, *supra* note 108, § 8.2.

sions for the patient. Moreover, drugs with even more likely and more serious side effects[356] are prescribed every day to people who have not even been advised of their risks.[357] Therefore, in accordance with both Title X requirements and the prevailing practice of allowing that patients make their own medical decisions, the pelvic exam requirement should be eliminated for its inconsistency.

Another requirement of Title X is that its programs "promote continued participation in the project by persons to whom family planning services may be beneficial."[358] The deterrent effect of the pelvic exam requirement discourages continued participation in Title X projects by many women to whom family planning services would be beneficial.[359] Such inconsistency in law is confusing and constitutes bad public policy.

D. Cost-Benefit Analysis

Cost-benefit analysis suggests that elimination of the pelvic exam requirement would be good public policy.[360] The harm caused by the pelvic exam requirement—as measured by the psychological distress inflicted by a pelvic exam[361] and the deterrent effect of the requirement[362]—is so disproportionate to any benefit derived from it[363] that it is clearly discordant with a cost-benefit analysis.[364] Based on such an analysis, the Institute for Women's Policy Research ("IWPR") has recently taken the official position

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[356] An example is corticosteroids. *See, e.g.*, University of Washington Orthopedics and Sports Medicine, *Corticosteroids for Arthritis* (Frederick A. Matsen III, ed.), *available at* http://www.orthop.washington.edu/arthritis/medications/corticosteroids/05 (last modified Mar. 8, 2002) (last visited Feb. 1, 2004); Hendrick Health System, Abilene Texas Hospital, *Corticosteroids* (discussing the risks of corticosteroids), *at* http://www.ehendrick.org/healthy/000374.htm (last visited Feb. 1, 2004).

[357] For example, hospitalized patients who are given medication, rather than a prescription to fill at a pharmacy, may not be fully informed of the medications' risks because no labeling accompanies the drugs.

[358] 42 C.F.R. § 59.5(b)(3)(iii) (1999).

[359] *See supra* Part VII.A.1.

[360] The legislature has acknowledged the significance of a cost-benefit ratio in its decisions surrounding implementation of Title X family planning programs. 136 CONG. REC. S13,677 (daily ed. Sept. 25, 1990) (statement of Sen. Kennedy).

[361] *See* MEAD, *supra* note 67, at 12 (discussing the "psychological effects of having to undergo a pelvic exam").

[362] *See supra* Parts III.B.1.c, VII.A.1, VII.A.3, and VII.B.

[363] This is especially true respecting the newer forms of contraception, which contain less estrogen (or none at all) than older forms and are deemed to be much more tolerable and beneficial for women. Seeley et al., *supra* note 33, http://www.mhhe.com/biosci/ap/seeleyap/repro/reading8.mhtml.

[364] *See* Trussell et al., *supra* note 18, at 502 (arguing that the economic savings and social benefits of contraception justify providing broader contraceptive coverage in family planning clinics where patients are informed about the contraceptives and voluntarily consent to their use); Stewart et al., *supra* note 49, at 2236 (suggesting that the health impact of a missed pelvic exam is less significant than the health impact of delayed or less effective contraception). The harm caused by the pelvic exam requirement outweighs the benefits even more obviously in asymptomatic, adolescent women. *See* Shafer, *supra* note 49, at 71–72.

of encouraging the FDA to make oral contraceptives available over the counter, despite the acknowledged potential risks associated with foregoing gynecological exams.[365] IWPR's research has indicated that the benefits of oral contraceptive use are so great that eliminating physician contact and counseling entirely would be warranted.

The proposal of this Article entails even fewer risks to women's health, as elimination of the pelvic exam requirement would not only not preclude, but would encourage, health care visits. There, counseling on the risks of the drug's use would be given to women, the opportunity for other health care services would be presented, and detection of contraindications to use and monitoring for resultant adverse effects would be provided through means less intrusive than a pelvic exam. In short, the consensus developed during the last decade supports eliminating the requirement of pelvic exams prior to prescription of oral contraceptives in order to establish good public policy.[366]

VIII. Proposal for Change

An alternative method for providing oral contraceptives to women in publicly funded clinics exists that would constitute good public policy and would not impermissibly infringe upon women's constitutional rights. In fact, this process would facilitate women's exercise of their constitutional right to reproductive autonomy via access to effective contraception. Under this proposal for change, physicians would be required to advise women of the possible risks associated with taking the drug without first undergoing a pelvic exam that could detect potential increased risks of side effects. Physicians would also be allowed, or even required, to encourage pelvic exams to promote the government's and women's interest in protecting their health.[367]

While a proposal to permit physicians to require pelvic exams when they deem it beneficial would be consistent with some arguments of this Article and would not unjustifiably infringe upon the constitutional rights involved, women should have complete power to veto pelvic exams and still receive their preferred method of contraception. Thus, after having been fully advised of the risks of choosing to forego a pelvic exam and begin an oral contraceptive regimen, a competent, adult woman would be able to sign an informed consent and waiver of physician and manufac-

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[365] Letter from Barbara Gault, Associate Director of Research, IWPR, to the FDA (June 27, 2000) (on file with author).

[366] Stewart et al., *supra* note 49, at 2232.

[367] Edelman & van Os, *supra* note 105, at 58 (stating that users of oral contraceptives "should be advised of these risks and encouraged to have periodical cervical evaluation," although not as a prerequisite to the drug's use).

turer liability[368] and receive a prescription without the exam.[369] The rationale is as follows: while guidelines and physician advice are important sources of information, the risk-benefit ratio associated with a drug's use will vary for each individual based on personal values and priorities.[370] The individual—not the physician—should ultimately make the determination of her clinical management, as she is the one who must live with the effects of that determination.[371] This is particularly true where there is no absolute contraindication to her use of the drug; the decision whether to use oral contraceptives is instead based on a weighing of factors. Furthermore, the established guidelines may not account for recent scientific data.[372] The requirement for pelvic exams was established in 1976, but the oral contraceptives typically prescribed now are newer and safer.[373] Recent studies have concluded that either there is no causal link between the drugs and cervical cancer or it is limited to a small subset of women who meet identifiable criteria,[374] such that "pelvic examinations . . . are not necessary for identifying women who should avoid [hormonal contraception] or need further evaluation before a decision about hormone use is reached."[375]

Consistent with this proposal, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research stated in 1982 that "the judgment about which choice will best serve well-being properly belongs to the patient" and that a physician must mention all alternatives to the patient, even if they are treatments which

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[368] Such a procedure is used in other areas of the law. RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1965) (providing that where the danger involved in the use of a product is unavoidable and the utility great, a drug manufacturer's liability may be avoided with proper warnings of the product's risk).

[369] Stewart et al., *supra* note 49, at 2236–38 (suggesting that women, rather than policymakers, are the appropriate decisionmakers concerning oral contraceptive use and arguing that women who are informed about the implications of a decision to forego a pelvic exam prior to beginning oral contraceptives should have the right to make that decision).

[370] Angela Mills, *Avoiding Problems in Clinical Practice After the Pill Scare*, 5 HUM. REPROD. UPDATE 639, 650 (1999), *reprinted in* REPRODUCTIVE CHOICES IN 2000: THE RELATIVE SAFETY OF CURRENT ORAL CONTRACEPTIVES 77, 88 (Robert Geoffrey Edwards & Jean Cohen eds., 2000) (stating that the utilization of guidelines in determining clinical management concerning contraception carries a risk of being too impersonal due to its failure to account for variations in risk-benefit ratios across couples).

[371] *Id.* (recognizing the woman's preference as an important factor for determining clinical management that is often neglected when guidelines concerning prescription decisions are utilized, and arguing that physicians' decisions are often imbued with their own personal prejudices or concerns and slanted in relation to their exposure to the general media).

[372] *Id.* (arguing that for guidelines concerning prescription of oral contraceptives to be useful, they must be reviewed and adjusted as new scientific data becomes available).

[373] *See, e.g.*, Arons, *supra* note 60, at 1125 n.207 (citing Linda Timm Wagner & Charlotte A. Kenreigh, *Choosing Oral Contraceptives*, 216 AM. DRUGGIST 64, 64–65 (1999)); Seeley et al., *supra* note 33, http://www.mhhe.com/biosci/ap/seeleyap/repro/reading8.mhtml.

[374] *See supra* Parts III.B.1.a and III.B.3; *see also, e.g.*, Arons, *supra* note 60, at 1125 n.207 (citing Wagner & Kenreigh, *supra* note 373, at 64–65).

[375] Stewart et al., *supra* note 49, at 2238.

the physician does not favor, so long as they are supported by "respectable medical opinion."[376] International medical standards support the safety of oral contraceptive use without a pelvic exam.[377] Many physicians and family planning service providers within the United States support elimination of the pelvic exam requirement[378] and urge periodic updating of recommendations concerning reproductive health care services based on scientific evidence.[379] These authorities constitute "respectable medical opinion" and, therefore, justify mandating provision of oral contraceptives without a pelvic exam as an available option under the position of the President's Commission.

The benefits of eliminating the pelvic exam requirement would be widespread and long-lasting. In the absence of any rational reason for its maintenance, it is unjustifiable to burden women with a barrier to services that takes its toll at both the individual and societal level. Removal of this requirement will protect substantive due process rights to contraception access, reproductive autonomy, and bodily privacy. Converting the exam requirement into an option will enforce the constitutional mandate for equal protection of women's and minorities' rights and uphold the prohibition against unconstitutional conditions on the exercise of fundamental privacy rights. In accordance with the crucial common goal of implementing beneficial public policy, the outdated pelvic exam requirement must be eliminated.

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[376] Rachel Benson Gold, *Conscience Makes a Comeback in the Age of Managed Care*, THE GUTTMACHER REPORT ON PUBLIC POLICY, Jan. 1998, at 1, 1, *available at* http://www.guttmacher.org/journals/tgr_archive.html (last visited Feb. 1, 2004).

[377] *See supra* note 82; *see also* Harper et al., *supra* note 74, at 13.

[378] *See supra* note 76 and accompanying text.

[379] *E.g.*, Stewart et al., *supra* note 49, at 2238 (stating that "decisions should not be made unacknowledged and by default because of historical beliefs perpetuated without scrutiny" and arguing that "recommendations for services that should comprise well-woman care should be updated periodically, based on sound scientific evidence").

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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

April 18, 2019

Cathy Williams, Interim President & CEO
Reproductive Health Services of Planned Parenthood
425 Forest Park Avenue
St. Louis, MO 63108

Re: Request for Deviation (RHS Health Center – Springfield, MO)

Dear Ms. Williams:

On February 1, 2019, Reproductive Health Services (RHS) submitted a Request for Deviations from some requirements of 19 CSR 30-30.070, for RHS' health center in Springfield, Missouri (attached).

The Department requested that RHS provide a code review sheet and architectural plans, as the request lacked sufficient information for DHSS to reasonably approve or deny the requests. In response, on February 8, 2019, RHS provided a facility floor plan (attached). The additionally provided information remained insufficient to make a determination. A mutually agreeable onsite walk-through was arranged for March 5, 2019, in order to gather sufficient information to respond to the submitted request.

On March 5, 2019, DHSS staff conducted a walk-through of the Springfield facility. RHS facilities manager, Chris Trull, represented RHS. The walk-through identified additional concerns related to the initial request submitted. Mr. Trull informed DHSS Deputy Administrator, David Lanigan, that the "measurements are not accurate" in the floor plan and request. Additionally, the floor plan did not accurately reflect additional walls inside the exam rooms. Furthermore, Mr. Trull was not familiar with RHS' plan regarding room locations, as identified in the request. Please find the below determinations regarding your request:

1. **Patient-Serving Corridors and Doors**

19 CSR 30-30.070(3)(B) & (C), states, *"(B) Corridors serving patients shall be at least six feet (6') wide; (C) All doors through which patients pass shall be at least forty-four inches (44") wide and of solid-core construction;"*

The RHS request indicates that patient-serving corridors are 4'7" wide and pass through doors are at least 32" wide and of hollow-core construction. The RHS request further asserts that the Springfield health center's current corridors and doors comply with the requirement at 19 CSR 30-30.070 (4)(B).

DHSS staff observed that the passageways at the facility are not adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit. The procedure room is constructed with barriers to maneuverability (inner walls and small spaces) not shown on the provided floor plan. As constructed, the layout and location of the existing doors into this

room do not open fully to allow for a wheelchair or a gurney to be easily moved out of the room in an emergency. In addition, the corridors serving patients and the door widths of the patient rooms other than the procedure room (noted as Exam Rooms #1, #2, and #3 on the floor plan provided to DHSS) are not of sufficient size to allow a stretcher to be promptly maneuvered in and a patient on a stretcher to be promptly maneuvered out of those rooms to a street-level exit. Only one exterior door meets the requirements of being 44" or wider.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(B) & (C). DHSS is willing to reconsider this request if RHS provides an adequate remediation plan that ensures prompt maneuverability of a patient on a stretcher into and out of the procedure room and other patient rooms in an emergency event.

2. **Construction Type**

19 CSR 30-30.070(3)(D) states, "*(D) One- (1-) story buildings shall be at least of Type II (111) protected noncombustible construction as described in Standard on Types of Building Construction 1979 published by the National Fire Protection Association;*"

The RHS request indicates that the Springfield facility is of "Type V (100) unprotected combustible construction." The RHS request further asserts that the Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the construction type of the facility is Type V (000), unprotected combustible construction. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility's construction is insufficient to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(D). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

3. **Fire Alarm**

19 CSR 30-30.070(3) (H) states, "*(H) A manual fire alarm break station shall be located near each exit and connected to a local audible alarm which can be heard throughout the facility;*".

The RHS request indicates that the Springfield facility does not have manual fire alarm break stations at each exit. The RHS request further asserts that the Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers.

DHSS staff confirmed that the facility lacks the required alarm break stations near each exit, connected to a local audible alarm. The facility is currently protected by three ABC-fire extinguishers and spot-type smoke detectors located in most, but not all rooms. The facility is not protected with a sprinkler system, is equipped with hollow-core doors and narrow passageways throughout. The facility is insufficiently equipped with fire alarm break stations to protect patient health and safety in the event of a fire.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(H). DHSS is willing to reconsider this request if an adequate sprinkler system is installed.

4. **Scrub Station**

19 CSR 30-30.070(3) (L) states, "*(L) Scrub-up facilities shall be knee- or foot-operated and provided at the rate of one (1) per procedure room. Scrub-up facilities shall be located outside but immediately available to the procedure room;*"

The RHS request indicates that the Springfield facility does have a scrub station located inside the room identified as the procedure room.

DHSS staff confirmed that the facility has a sink in the procedure room that is not knee-or-foot operated, as required.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(L), provided the current sink is replaced with a knee or foot operated scrub station, as noted in the request and it is physically separated by a wall or partition from the patient and procedure equipment to prevent contamination while scrubbing for procedures.

5. **Procedure Room**

19 CSR 30-30.070(3) (M) states, "*(M) Procedure rooms shall have the following: 1. A minimum length and width of twelve feet (12'); 2. A minimum ceiling height of nine feet (9'); 3. A door with a minimum width of forty-four inches (44"); and 4. There shall be no windows in the room except there may be a fixed-view window in the wall between the procedure room and the adjacent corridor;*"

The RHS request indicates that the Springfield facility's procedure room was 12'6" by 11'6", the ceiling height is 7'9 and the door width is 36." The RHS request further asserts that the dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

RHS representative, Mr. Trull, identified Exam Room #4 as the procedure room. The measurements and configuration of Exam Room #4 differed from the floor plan provided to DHSS. According to the floor plan, the measurements of the room are "16-9 ½" by "13'". Further, the floor plan nor the measurements in the waiver request account for interior walls that break up the room, limiting mobility. Mr. Trull, acknowledged the measurements provided by RHS were "not accurate." DHSS staff observed that the procedure table is located in an alcove that is 7' in width and separated from an adjacent open area with a 4'6" wing-wall. The identified procedure room is insufficient in size and configuration to allow medical staff to move freely in the event of an emergency (see attached photos).

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(M)(1) and (3). DHSS approves the request for deviation from 19 CSR 30-30.070(3)(M)(2). DHSS is willing to reconsider the denied aspects of this request if RHS provides an adequate remediation plan that ensures prompt

maneuverability of a patient on a stretcher into and out of the procedure room in the event of an emergency.

6. **Recovery Room**

19 CSR 30-30.070 (3) (N) states, "*(N) The recovery room shall be separated from the procedure room and be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner;*"

The RHS request indicates that the Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner.

RHS representative, Mr. Trull, could not identify which room would be utilized as the recovery room. Mr. Trull stated he was "not sure of the plan" and didn't think RHS had decided where the room would be located. Without knowing which room would be the recovery room, DHSS cannot determine whether a deviation is warranted.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(N). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room.

7. **HVAC**

19 CSR 30-30.070 (3)(O) states, "*(O) The procedure room and recovery room shall be provided with a minimum of six (6) air changes per hour. Air supplied to all areas shall be filtered through a filter with at least a twenty-five percent (25%) efficiency rating;*"

The RHS request indicates that the Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. Mr. Trull was unable to provide documentation of the facility's current air exchange rate or current efficiency rating for evaluation. Further, Mr. Trull could not identify the location of the recovery room, which restricts DHSS's ability to determine whether a deviation is warranted.

Lastly, the fact that DHSS determined in 1987 that the requirements for then-existing abortion facilities need not include a minimum number of air changes per hour or a filter with a minimum efficiency rating does not mean—as suggested in the RHS request—that requiring these things for facilities constructed after the rule was promulgated in 1987 has no effect on improving patient health or safety. This provision of this rule, like others discussed in this letter, was promulgated in 1987 under DHSS's authority in section 197.225 RSMo to assure quality patient care through standards that insure the health, safety, and comfort of patients. Requirements of minimum air changes per hour are also required by DHSS for ambulatory surgical centers generally and birthing centers. Any deviations from this rule, as with others, would need to be based on a legitimate and persuasive reason provided by the requester. Here, the only reason provided for a deviation is that DHSS does not require in the rule minimum air changes and filter efficiency ratings for then-existing abortion facilities in 1987. This reason is not sufficient. The reported cost (as alleged in the request) of $2.26 million to comply with the rule in total, moreover, provides no indication how much of that total would be attributable to these particular

requirements. And as noted above, Mr. Trull could not provide documentation showing the current ventilation capabilities. Under these circumstances, DHSS cannot reasonably grant a deviation from a rule designed to insure the health, safety, and comfort of patients.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(O). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the recovery room and provides adequate information that allows DHSS to meaningfully assess the Springfield facility's current air exchange rate and efficiency rating.

8. **Personnel-Change Room**

19 CSR 30-30.070 (3) (P) states, "*(P) Personnel change rooms shall be provided for each sex and located convenient to the procedure room. Each change room shall be equipped with a toilet and lavatory;*"

The RHS request indicates that the Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory.
RHS representative, Mr. Trull, identified a restroom, in close proximity to the procedure room as a personnel-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(P).

9. **Ceiling-Mounted Surgical Light**

19 CSR 30-30.070 (3) (R) states, "*(R) The procedure room shall be equipped with a ceiling-mounted surgical light, operating table or a conventional gynecological examining table with accessories, closed cabinets for equipment, and sufficient tables to hold an emergency tray and other necessary equipment;*"

The RHS request indicates that the Springfield facility will equip the procedure room with a wall-mounted surgical light, which would be better angled for the procedures they provide.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(R) based on the current configuration and available space within the identified procedure room, which is limited by an interior wall directly to the left of the room entrance. This wall does not allow sufficient space in the room for mounting the surgical light on the wall. DHSS is willing to reconsider this request if modifications are made to the room that allow sufficient space to mount the surgical light on the wall.

10. **Sterilization Room**

19 CSR 30-30.070 (3) (V) states, "*(V) The sterilizing room shall be equipped with a steam sterilizer, counter and sink, and storage space for clean supplies. Air pressure in this room shall be positive in relation to adjacent areas;*"

The RHS request indicates that the air pressure in the Springfield facility's sterilizing room is not positive in relation to the adjacent areas. Mr. Trull was unable to identify the location of the sterilization room or provide documentation of the room's current air pressure for evaluation. As with the recovery

room, this restricts DHSS's ability to determine whether a deviation is warranted. And for similar reasons set forth above with respect to the request for deviation from the ventilation requirements, the mere fact that DHSS did not express this as a requirement for abortion facilities in existence when the rule was promulgated in 1987 is not sufficient reason to justify deviation from the rule.

DHSS denies the request for deviation from 19 CSR 30-30.070(3)(V). DHSS is willing to reconsider this request if RHS identifies the room that will be utilized as the sterilizing room and provides adequate information that allows DHSS to meaningfully assess the sterilizing room's air pressure in relation to adjacent areas.

11. **Patient-Change Rooms**

19 CSR 30-30.070 (3) (Y) states, "*(Y) At least two (2) patient change rooms with secure storage for personal effects shall be provided;*"

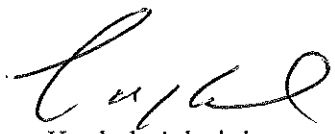
The RHS request indicates that the Springfield facility has one patient-change room.

DHSS approves the request for deviation from 19 CSR 30-30.070(3)(Y) under the condition that patient belongings travel with the patient in a secure container, it uses only one (1) procedure room and does not use the procedure room as the change room.

The deviation approvals contained in this correspondence may be revoked any time DHSS determines: (1) that patient care or safety may be compromised, (2) that the facility is not in full compliance with applicable rules, or (3) the facility fails to adhere to all conditions of the approved deviations.

Thank you again for your willingness to coordinate an on-site walk-through of the Springfield facility. Should you have further questions regarding this letter, please contact David Lanigan at David.Lanigan@health.mo.gov or by calling (573) 526-1864.

Sincerely,



William Koebel, Administrator
Section for Health Standards and Licensure
Division of Regulation and Licensure
Department of Health and Senior Services

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Planned Parenthood of the St. Louis Region and Southwest Missouri

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February 1, 2019

Via email to: William.Koebel@health.mo.gov

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: *Request for Deviation*

Dear Mr. Koebel:

Pursuant 19 CSR 30-30.070(2), I write to request deviations/waivers of certain physical standards for Reproductive Health Services of Planned Parenthood of the St. Louis Region's (RHS) health center in Springfield.

The physical facility restrictions in 19 CSR 30-30.070 prevent us from providing surgical abortion in our Springfield health center. RHS remains committed to providing abortion services to the women of Southwest Missouri, and therefore by this letter seeks waivers of those requirements it cannot meet. We request the Department "exercise[] the Waiver Provision" "with sufficient flexibility" and reasonableness. *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, 903 F.3d 750, 756–57 (8th Cir. 2018).

Abortion Safety

As you know, RHS has safely provided abortion services in Missouri for many years. The physical facility restrictions are medically unnecessary and do not improve the health and safety of our patients seeking abortion care. Indeed, the Department has recognized as much when it waived a number of medically unnecessary restrictions in a 2010 settlement with the Columbia health center.

Abortion is one of the safest medical procedures in the United States. As the National Academies of Sciences, Engineering, and Medicine—which recently conducted a systematic review of the safety and quality of care of abortion in the United States—found, abortion in the United States is safe. In particular, first-trimester aspiration

abortion, which we seek to provide in the Springfield health center, "is a minimally invasive and commonly used gynecological procedure," including "in cases of early pregnancy loss (miscarriage)."[1] Aspiration abortion is effective at terminating an early pregnancy in more than 99% of those provided, and complications from first-trimester aspiration abortion occur in approximately 1.26% of patients—and serious complication in less than 0.02%.[2] Aspiration abortion may require no or only minimal sedation.

As the National Academies observed, "[a]spiration abortions are performed safely in office and clinic settings."[3] Abortion-specific regulations—such as the physical facility restrictions in 19 CSR 30-30.070—serve only to "diminish" the quality of care women receive by "limit[ing] the number of available providers."[4]

Requested Waivers

Against the backdrop of abortion's demonstrated safety, and given that the current facility is sufficient to protect patient health and safety, we make the following waiver requests. We note at the outset that we are committed to working with the Department on these issues so that we can begin providing abortion services to our patients at the Springfield health center. We also note that the Springfield facility meets many of the requirements in 19 CSR § 30-30.070(4), which applies to facilities existing at the time the regulation was adopted, and therefore, demonstrates the Department's understanding that these provisions are sufficient to protect patient health and safety.

1. **Patient-Serving Corridors and Doors**

Subsections 30-30.70(3)(B) & (C) require patient-serving corridors be at least 6' wide and doors through which patients pass be at least 44" wide and of solid-core construction. Patient-serving corridors at the Springfield center are 4'7" wide and doors through which patients pass are at least 32" wide and of hollow-core construction.

The Springfield health center's current system of corridors and doors adequately protect patient health and safety by allowing a patient to be moved by stretcher from any point in the facility to the outside via the main entrance. Indeed, the Springfield health center's current corridors and doors comply with the requirement at 19 CSR § 30-30.070(4)(B) that the system of corridors and passageways be "adequate in size and arrangement to allow a patient on a stretcher to be moved from any point in the abortion facility to a street-level exit." We also note that the Department agreed to a similar corridor dimension for the Columbia health center in a 2010 settlement agreement.

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[1] Nat'l Acad. of Sciences, Engineering & Medicine, The Safety and Quality of Abortion Care in the United States 2-12 (2018).
[2] *Id.* at 2-12 to 2-13 (citing Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 124 Obstetrics & Gynecology 175 (2015)).
[3] *Id.* at S-8.
[4] *Id.* at S-10.

2. Construction Type

Subsection 30-30.70(3)(D) requires one-story buildings be at least of Type II (111) protected noncombustible construction as described in *Standard on Types of Building Construction* 1979 published by the National Fire Protection Association. The Springfield facility is of Type V (100) unprotected combustible construction.

The Springfield health center's construction is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The higher fire-safety rating is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

3. Fire Alarm

Subsection 30-30.70(3)(H) requires a manual fire alarm break station be located near each exit and connected to a local audible alarm that can be heard throughout the facility. The Springfield health center does not have manual fire alarm break stations at each exit.

The Springfield health center's current fire system is sufficient to protect patient health and safety, because the Springfield health center has in place appropriate fire-detection devices and fire extinguishers. The adequacy of the Springfield health center's facilities is demonstrated by the fact that the building complies with all applicable building and fire codes, as well as with the requirements at 19 CSR § 30-30.070(4)(A) that smoke detectors be located in all rooms and in corridors at 30' intervals.

The requirement is not necessary to patient health and safety because the nature of the services provided at the health center, including the lack of services under anesthesia or moderate or deep sedation and the lack of procedures requiring an incision, means that there would not be unusual delay in patient evacuation in the unlikely event of a fire.

4. Scrub Station

Subsection 30-30.70(3)(L) requires a scrub-up facility be knee- or foot-operated and be located outside the procedure room. The Springfield health center has a scrub station located inside the procedure room. The requirement that the scrub station be located outside the procedure room does not protect patient health or safety. The Springfield

center complies with the requirement in 19 CSR § 30-30.070(4)(F) that the scrub-up facility be located convenient to the procedure room.[5]

5. Procedure Room

Subsection 30-30.70(3)(M) requires that all procedure rooms be a minimum of 12' length and width, 9' ceiling height, and doors with a width of at least 44". The Springfield facility's procedure room's dimensions are 12'6" by 11'6", ceiling height of 7'9", and door width of 36".

The dimensions of the Springfield health center's procedure room are sufficient for aspiration procedures and to protect patient health and safety, because they allow the medical staff to move freely in providing patient care, both in the ordinary course of practice and in the event of an emergency.

Further, the Springfield health center's existing procedure room meets the requirement at 19 CSR § 30-30.070(4)(E) that it be "adequately equipped, supplied, and staffed to safely perform abortions," which the Department has determined is sufficient to protect patient health and safety; this requirement does not specify minimum dimensions. The room is of sufficient size to fit a gynecologic examining table with accessories, a closed cabinet for equipment, and tables to hold an emergency tray and other necessary equipment.

Requiring compliance with the nine-foot ceiling height would not advance patient health and safety, because such ceiling height requirements generally are intended to facilitate installation of a ceiling-mounted surgical light. These lights would not be appropriate to the procedures done at the Springfield health center, for the reasons given below under request no. 9. Requiring compliance with the 44" door width would not advance patient health and safety at the Springfield health center because, as discussed above under request no. 1, the current system of corridors and doors allows rapid patient evacuation in the event of an emergency. Finally, we note that the Department agreed to similar dimensions of 12' length, 9' 0.5" width, and 8' 6"' height for the Columbia health center in a 2010 settlement agreement.

6. Recovery Room

Subsection 30-30.70(3)(N) requires the recovery room be of sufficient size for four recovery recliners or beds with 3' of clear space on both sides and at the foot of each recliner or bed.

The Springfield facility's recovery room is of sufficient size to accommodate three recovery recliners with 3' of clear space on both sides and at the foot of each recliner. We do not anticipate scheduling—and will agree to not schedule—more patients than the recovery room can accommodate. We note that the Department recently approved a deviation from this requirement for the Columbia facility to permit three recliners.

[5] We acknowledge our current scrub sink is not knee- or foot-operated. We will replace the current sink with a knee- or foot-operated if the Department approves this waiver.

7. HVAC

Subsection 30-30.70(3)(O) requires the procedure and recovery rooms be provided with a minimum of six air changes per hour and filtered through a filter with at least a twenty-five percent (25%) efficiency rating. The Springfield facility does not have a ventilation system that allows for a minimum of six air changes per hour that filters the air with at least 25% efficiency rating. This requirement is not necessary for patient health or safety, particularly since surgical abortion does not require a sterile operating room environment, as demonstrated by its omission in 19 CSR § 30-30.070(4).

8. Personnel-Change Room

Subsection 30-30.70(3)(P) requires personnel-change rooms be provided for each sex, located convenient to the procedure room, and equipped with a toilet and lavatory. The Springfield facility has one gender neutral personnel-change room that is located convenient to the procedure room and equipped with a toilet and lavatory. We note that the Department agreed to a similar deviation for the Columbia health center in a 2010 settlement agreement.

9. Ceiling-Mounted Surgical Light

Subsection 30-30.70(3)(R) requires the the procedure room be equipped with a ceiling-mounted light. The Springfield facility's procedure room would be equipped with a walled-mounted surgical light, which is better angled for the procedures that would be provided. We note that the Department agreed to similar deviation for the Columbia health center in a 2010 settlement agreement.

10. Sterilizing Room

Subsection 30-30.70(3)(V) requires that air pressure in the sterilizing room be positive in relation to adjacent areas. The air pressure in the Springfield health center's sterilizing room is not positive in relation to adjacent areas. This requirement is not necessary for patient health or safety, as demonstrated by its omission in 19 CSR § 30-30.070(4).

11. Patient-Change Rooms

Subsection 30-30.70(3)(Y) requires there be at least two patient-change rooms with secure storage for personal effects. The Springfield facility has one patient-change room. We note that the Department agreed to deviation for the Columbia health center in a 2010 settlement agreement such that there could be one patient-change room if the patient traveled with her belongings in a secure container. We will agree to do the same or provide the patient with secure storage in the patient-change room.

Burdens

Complying with the physical facility requirements in 19 CSR 30-30.070 at our Springfield facility would be prohibitively expensive and burdensome. A recent survey of the facility by a licensed architect found that it would cost $2.26 million to remodel the Springfield health center to meet the requirements in 19 CSR 30-30.070, which is approximately the same amount to construct a new facility. Construction would take

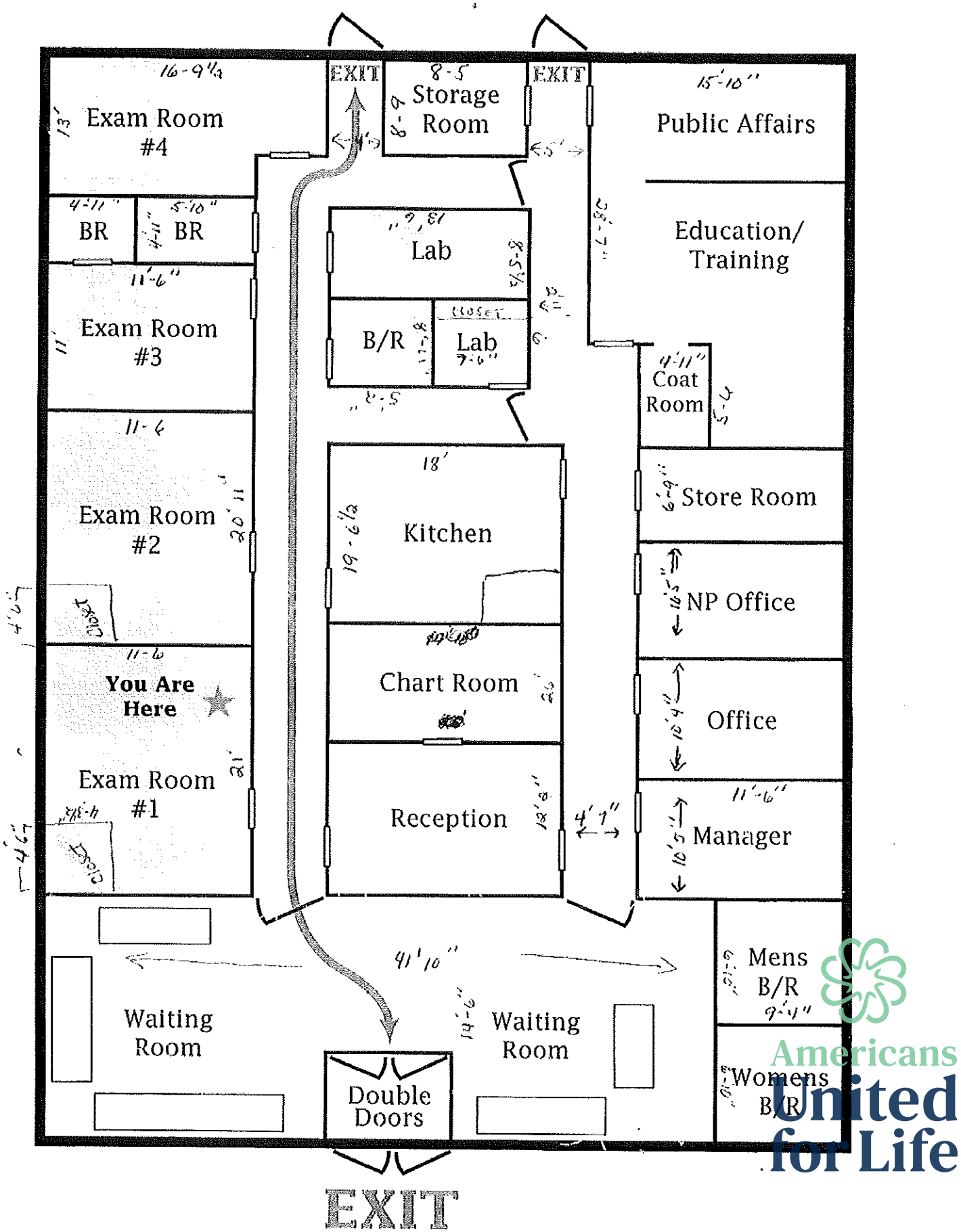
approximately eight months to complete and include complete removal and installation of the roof and exterior walls. As a result, such construction would completely disrupt the critical health services currently provided there, including family planning services that help prevent unplanned pregnancies.

Please let me know if you have any questions regarding this request. I look forward to hearing your prompt response.

Sincerely,

Janice Thomas
Vice President of Patient Services & Research

Americans United for Life



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Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

May 20, 2019

Cathy Williams, Interim President & CEO
Reproductive Health Services of Planned Parenthood
425 Forest Park Avenue
St. Louis, MO 63108

Re: POC Rejection / Incomplete Investigation

Dear Ms. Williams:

On April 9, 2019, our Bureau of Ambulatory Care received your Plan of Correction as a result of a Licensure inspection conducted on March 13, 2019. Your Plan of Correction is not acceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable, and we recommend that you submit an amended Plan of Correction that addresses these issues promptly. These areas are as follows:

In reference to the deficiency identified in ***L-1076***- Regarding patient #10, the Statement of Deficiencies (SOD) misidentified Staff AA as the physician who induced the medication abortion and will be updated to reflect the removal of that statement (revised SOD attached). Second, in accordance with section 188.027.6 RSMo, the physician performing the physician portion of the informed consent must be the same physician who performs or induces the abortion. A supervising physician who is merely present in the building without taking any active role in performing or inducing the abortion—while a resident or fellow actually performs or induces the abortion—does not "perform or induce" the abortion under the statute. Your proposed Plan of Correction states that, in the two specific instances cited in the SOD, the supervising physician who carried out the physician portion of the informed consent actively participated in inducing the abortion. But our investigation commenced on April 3, 2019, has identified additional instances in which medical records indicate that the physician who carried out the physician portion of the informed consent differed from the physician who performed or induced the abortion. We have been unable to verify the fact or extent of your compliance with this requirement because several physicians identified in those records have refused to participate in interviews. The Plan of Correction fails to provide adequate assurance of compliance and fails to identify the systemic changes that will be implemented to ensure that the deficient practice will not recur. The description must be specific, realistic and complete.

In reference to the deficiency identified in ***L-1103***- A pelvic examination must be completed prior to every abortion for the purpose of "*determining the duration of gestation, identifying preexisting medical or other complications, and detecting factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management*" in accordance with 19 CSR 30-30.060(2)(D) (emphasis added). Inspectors found that pelvic examinations were performed immediately prior to the actual abortion procedure in the case of surgical abortions, not meeting the purpose of the

requirement, which as noted above includes "detecting factors which could influence the choice of the procedure." Additionally, your policy indicates a pelvic examination is completed for medication abortions only "when indicated (e.g., vaginal bleeding or abdominal/pelvic pain, or as required by Missouri regulations)." This suggests that there may be times when a pelvic examination would not be required by Missouri regulations, which is not correct under 19 CSR 30-30.060(2)(D). The Plan of Correction fails to identify the systemic changes that will be implemented to ensure that the purpose of the rule is met and the deficient practice will not recur. The description must be specific, realistic and complete.

In reference to the deficiency identified in ***L-1131***- Please provide more specific information regarding the frequency and type of audits that will be completed to ensure compliance is maintained.

Please submit a revised Plan of Correction with the above mentioned information as soon as possible via email to BAC@health.mo.gov or fax to (573) 751-6648 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570. I have attached a detailed instruction sheet for your reference.

On April 3, 2019, you were notified of a complaint investigation regarding Reproductive Health Services of Planned Parenthood of the St. Louis Region (RHS). As part of the investigation, interviews were requested with your physician abortion providers. To date, RHS has been unable to produce some physician abortion providers, as identified in the medical records, for interview with Department Inspectors. As a result of the investigation, more than thirty (30) potential deficient practices were identified, including but not limited to those discussed above. Please note that the Department cannot complete our investigation as required until we interview the physicians involved in the care provided in the potential deficient practices, noted above, at the facility. Historically, RHS has always provided physicians for interview. This is also the standard practice across all regulated provider types.

The Department is in receipt of your licensure renewal application, received on May 16, 2019. As I have informed RHS staff since April 3, 2019, the complaint investigation needs to be completed and any deficiencies resolved before the expiration of RHS's license on May 31, 2019. And on April 22, 2019, RHS was also notified in relation to the the requested physician interviews of the prohibition in 19 CSR 30-30.050(2)(I), which states: "No license shall be issued or renewed by the department until the department has inspected the facility and determined that it is in compliance with all requirements of applicable statutes and regulations." As indicated above, until the Department interviews the physicians, we cannot complete our investigation and determine compliance with all applicable statutes and regulations.

Sincerely,

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/13/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/11/19 to 03/13/19 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		4/30/19

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L 069	Continued From page 1 2. Review of the facility's records of fire drills showed that the most recent fire drill occurred on 11/30/18 and the previous drill occurred on 06/02/17. (Note: The time between drills was more than 12 months). The list of staff on the drill from 11/30/18 showed 30 names and 10 were indicated as having been part of the drill. 3. During an interview on 03/11/19 at 4:15 PM, Staff N, Clinical Quality Improvement Manager, stated that she did not know why the fire drills were more than 12 months apart and that no physicians were listed as participating as there were none onsite that day.	L 069		
L1069	19 CSR 30-30.060(1)(A)(1) The governing body shall have full legal The governing body shall have full legal responsibility for determining, implementing, and monitoring policies governing a facility's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment and in accordance with all legal requirements and standards of care. This regulation is not met as evidenced by: Based on record review the facility failed to ensure all policies were written to maintain compliance with all regulatory requirements for obtaining a complete medical history to include a pelvic examination. Findings included: 1. Licensure regulations at 19 CSR 30-30.060 (2)(D) require a written medical history shall be obtained for each patient. A health assessment	L1069		4/30/19

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L1069	Continued From page 2 including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Training's Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical abortion when medically indicated - current practice.	L1069		
L1076	19 CSR 30-30.060(1)(A)(8) The governing body, ensure abortion facility The governing body, through the administrator, shall ensure that the abortion facility abides by all applicable state and federal laws and regulations. This shall include, but not be limited to, compliance with Chapter 188, RSMo. This regulation is not met as evidenced by:	L1076		4/30/19

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L1076	Continued From page 3 Based on policy review, record review and interview, the facility failed to ensure the physician who obtained the informed consent was the physician who performed or induced the abortion for two (#7 and #10) of 10 patients' abortion medical records reviewed. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. The physician who is to perform or induce the abortion shall provide the information required in section 188.027.6, RSMo, orally and in person to the patient at least seventy-two (72) hours before the abortion. 2. Review of the facility's policy titled, "Consent and Informed Consent," dated 06/16, showed per Missouri SB (Senate Bill) 793 and SB5 ALL women who request an abortion in Missouri must meet with a Qualified Health Professional and the physician who will provide the abortion procedure for consultation at least 72 hours prior to an abortion procedure (or informed consent may be given by physician only). 3. Review of Patient #7's medical record showed: - On 11/15/18, Staff GG, Medical Doctor (MD), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion." - On 11/20/18, Staff AA, MD, administered Mifepristone (stops the pregnancy from growing and is the first of two medications administered in a medication-induced abortion). 4. During an interview on 03/12/19 at 1:04 PM,	L1076		

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L1076	Continued From page 4 Staff A, Director of Surgical Services, stated that: - Staff AA was a fellow (physician who has completed their residency and elects to complete further training in a specialty) who worked with Staff GG. - The Mifepristone agreement (medication agreement form signed by the patient and provider [physician] that explains that the medications will end the pregnancy, what to expect, and directions) was signed by the patient and Staff AA. 5. Review of Patient #10's medical record showed: - On 08/29/18, Staff FF, Doctor of Osteopathic Medicine (physician whose training focused on emphasizing a whole-person approach to treatment and care), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion." - On 09/05/18, Staff AA attempted a surgical abortion, which was unsuccessful. - A separate document generated by Staff FF that included: * "I was present for the procedure and agree with the treatment and follow up plan(s)." * "TV (Trans-vaginal) U/S (ultrasound) was able to confirm the path, but given the unique position of the uterus and patient's discomfort, coupled with early gestational age, we opted to stop the SAB (surgical abortion) and proceed with MAB (medical abortion)." 6. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that: - The supervising physician was responsible for care of the patient; - The supervising physician for Patient #7 was	L1076		

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L1076	Continued From page 5 Staff GG; - Staff GG did not complete a supervisory note for Patient #7; - Staff AA could administer the Mifepristone without the supervisory physician in the room; - Staff GG was in the room during the surgical abortion attempt on Patient #7 (performed by Staff AA); and - The supervising physician for Patient #10 was Staff FF.	L1076		
L1103	19 CSR 30-30.060(2)(D) A written medical history shall be obtained A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to perform the pelvic examination at a time that could influence the choice of the planned procedure and pre-operative management for nine (#1, #2, #3, #4, #5, #6, #7, #8, and #10) of nine patients' abortion medical records reviewed. The Abortion Facility does an average of 216 cases per month. On the first day of the survey,	L1103		4/30/19

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L1103	Continued From page 6 there were 21 procedures. Findings included: 1. 188.027 states that Consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion: 1(f)- the physician who is to perform or induce the abortion, a qualified professional, or the referring physician informs the woman of the gestational age of the unborn child at the time the abortion is to be performed or induced. 30-30.060 (D) A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Trainings Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical abortion when medically indicated - current practice.	L1103		

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L1103	Continued From page 7 3. Review of medical records for Patient #1, #2, #3, #4, #5, #6, and #8 with admission dates ranging from 11/17/18 to 02/23/19 for a surgical abortion showed documentation included findings from a pelvic examination, but the date and time of the pelvic examination were not documented. 4. Review of Patient #7's medical record, dated 11/20/18, showed the patient was admitted for a surgical abortion. The physician's undated and untimed note of the pelvic examination included, "Exam limited by body habitus." A medical record entry, dated 11/20/18 at 1:40 PM, showed Staff B, Registered Nurse, documented, "Per (Staff GG, Medical Doctor [MD]) they were unable to perform in clinic procedure (surgical abortion) so patient will proceed with medication abortion." 5. Review of Patient #10's medical record, dated 09/05/18, showed the patient was admitted for a surgical abortion. Documentation included findings from a pelvic examination, but the date and time of the pelvic examination were not documented. (Note: The surgical abortion was unsuccessful so the plan changed to a medication-induced abortion.) 6. During an interview on 03/13/19 at 11:50 AM, Staff A, Director of Surgical Services, stated that: - The pelvic exam was done after the consenting process and pre-operative phase; - Pelvic exams were done right after the time out (intentional pause immediately before starting the surgical procedure when a final verification is made to confirm the correct patient, surgery, side, implant, and any special requirements); - Right after the pelvic exam, medications were given and then the procedure was completed;	L1103		

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L1103	Continued From page 8 and - The medical records did not include the date and time of the pelvic exam. 7. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that: - Routinely, they performed the time out, the pelvic exam, administered the medication, and then performed the procedure. - They did the pelvic exam before going into the uterus.	L1103		
L1116	19 CSR 30-30.060(2)(N) Facilities performing surgical,emergency drug Facilities performing surgical procedures shall have emergency drugs, oxygen, and intravenous fluids in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine, and endotracheal equipment shall be located in the clinical area for immediate access. This regulation is not met as evidenced by: Based on state statute, nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained the necessary endotracheal equipment (equipment used to provide respiration when the patient is unable to breath for themselves) readily available to manage a respiratory emergency; - Staff were familiar with the location and operation of emergency equipment; and - Policies were developed to ensure staff orientation and knowledge validation for the location and use of emergency supplies; The Abortion Facility does an average of 216	L1116		4/30/19

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L1116	Continued From page 9 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the 2011 Missouri Revised Statutes TITLE XII PUBLIC HEALTH AND WELFARE Chapter 197 Medical Treatment Facility Licenses Section 197.230 showed: - The department of health and senior services shall make, or cause to be made, such inspections and investigations as it deems necessary. The department may delegate its powers and duties to investigate and inspect ambulatory surgical centers or abortion facilities to an official of a political subdivision having a population of at least four hundred fifty thousand if such political subdivision is deemed qualified by the department to inspect and investigate ambulatory surgical centers. The official so designated shall submit a written report of his or her findings to the department and the department may accept the recommendations of such official if it determines that the facility inspected meets minimum standards established pursuant to sections 197.200 to 197.240. - In the case of any abortion facility, the department shall make or cause to be made an unannounced on-site inspection and investigation at least annually. Such on-site inspection and investigation shall include, but not be limited to, the following areas: (1) Compliance with all statutory and regulatory requirements for an abortion facility, including requirements that the facility maintain adequate staffing and equipment to respond to medical emergencies. 2. Review of the Association of PeriOperative	L1116		

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L1116	Continued From page 10 Registered Nurses "Guideline for Care of the Patient Receiving Moderate Sedation/Analgesia (a condition in which the patient exhibits a mildly depressed level of consciousness and an altered perception of pain but retains the ability to respond appropriately to verbal or tactile stimulation)," dated 2018, showed: - Recommendation III.c.4. * Monitoring equipment (e.g., pulse oximetry (device that measures the oxygen saturation of arterial blood), Electrocardiogram (ECG - measures electrical activity all over the heart), capnography (the monitoring of the concentration carbon dioxide in the respiratory gases), blood pressure measurement devices, oxygen source, masks and cannulas, suction source, tubing, and tips, and oral and nasal [through the nose] airways) should be working properly, and immediately available in the room where the procedure is being performed. - Recommendation III.e. * Emergency resuscitation equipment and supplies should be immediately available in every location in which moderate sedation is administered. - Recommendation III.e.1. * Emergency equipment and supplies should include: Airway and ventilatory equipment (e.g., laryngoscopes (a diagnostic tool with a blade, light, and mirrors, used to examine the larynx [hollow organ in the throat that forms an air passage to the lungs]), endotracheal tubes (ETT- a breathing tube inserted into the airway to keep the airway open), laryngeal mask airway (LMA - a medical device that keeps a patient's airway open during anesthesia or unconsciousness), oral and nasal airways;	L1116		

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L1116	Continued From page 11 3. Review of the facility's policy titled, "Emergency Response Protocol and Procedure for Emergency Transfer of Patients in Life Threatening Situations," dated 02/19, showed: - When an emergency is recognized by staff they will respond to the patient in crisis and notify physician and Registered Nurse (RN)/Licensed Practical Nurse (LPN). - Basic Life Support (BLS - a level of medical care which is used for victims of life-threatening illnesses or injuries until they can be given full medical care) services and supportive care will be started as indicated. - Treating physician will direct patient care and designate team members to carry out tasks as necessary. * Be sure to start with the ABCs (Airway, Breathing, Circulation). - RN/LPN who comes to the room should assess ABCs and should ask treating physician for report regarding any other equipment (e.g. intravenous (small catheter inserted into a vein for administering medication and fluid) access, oxygen, and ultrasound) or medications needed. (Note: The policy failed to identify the emergency equipment necessary to treat seizures, bleedings, anaphylactic shock, respiratory arrest, and cardiac arrest and other life threatening emergencies and failed to address the need for staff orientation and training on the locations and operation of emergency equipment.) 4. Review of the facility's undated document titled, "Emergency Box: Medication and Supplies," showed the emergency box checklist failed to include suction equipment, i.e., suction device (plastic suction tip used to suction secretions from the mouth and throat) and endotracheal equipment (equipment used to	L1116		

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L1116	Continued From page 12 manage an open airway, i.e., endotracheal tubes, endotracheal tube introducers [device used to assist in obtaining an airway] and laryngoscope handle and blades). 5. Review of the facility's undated checklist titled, "Quality Management (QM) Site System Review," showed: - The document was to be completed monthly by the Surgical Services Manager/Delegate and included: - Emergency Equipment * Audited by nursing supervisor (blank for initials). * Resuscitative equipment; and * Cart with emergency supplies & weekly checklist current. (Note: The checklist failed to contain a list of specific emergency or resuscitative equipment to be checked.) 6. Observation on 03/11/19 at approximately 1:45 PM showed: - A portable suction machine in supply storage room #2; - No suction equipment in three of three procedure rooms; and - No suction equipment in the pre/post procedure area. 7. During an interview on 03/12/19 at 9:25 AM in the pre/post procedure area, Staff O, Advanced Practice Registered Nurse (APRN), Clinical Manager, stated that: - There was no suction in the procedure rooms or pre/post procedure area. - She did not know where the suction machine was located. - Staff needed an in-service on location of	L1116		

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L1116	Continued From page 13 emergency equipment. 8. Observation on 03/12/19 at 9:30 AM in the pre/post procedure area showed: - An emergency box with emergency medications and supplies. * The emergency box did not contain suction supplies (suction tips or cannulas) or endotracheal equipment. During an interview upon the observation, Staff B, Registered Nurse (RN), stated that: - There was no suction supplies or endotracheal equipment in the pre/post area. - She did not know what emergency supplies were in the procedure rooms, she was only responsible for the pre/post procedure area. - She had worked at the facility for approximately three years. - She did not know where the suction machine was located. During an interview upon the observation, Staff O stated that she did not know where the endotracheal tubes were located. 9. During an interview on 03/12/19 at 10:05 AM, Staff EE, Physician, stated that: - If they had a patient that needed intubation he would use a LMA. - The LMA's were with the emergency supplies in the procedure rooms. - The facility had LMAs, oxygen, and suction for endotracheal equipment. - Given the facility's proximity to a hospital and EMS response time he had determined those supplies were sufficient for the facility. 10. During an interview on 03/12/19 at 10:10 AM,	L1116		

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L1116	Continued From page 14 Staff H, Surgical Scrub Technician (staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), Patient Flow Coordinator, stated that: - The suction machine was in the sterile supply storage room. - They did not have suction tips or catheters for oral suction of the patient. - She did not know if the facility had laryngoscope handles and blades. - They did not have LMAs. 12. During an interview on 03/12/19 at 10:15 AM, Staff A, Director of Surgical Services, stated that she did not know where the suction tips or laryngoscope handles and blades were located or if they had them. 13. Observation on 03/12/19 at 10:20 AM of procedure room #3 and two sterile supplies closet showed there were no LMA or suction tips available for the facility. 14. Observation on 03/12/19 at 10:35 AM of sterile storage room #2 showed: - The laryngoscope handles and blades were stored together in a factory storage container on the top shelf. - The handles and blades had not been cleaned, high level disinfected, or packaged to prevent cross-contamination. (Note: The handles and blades were not ready for patient use.) During an interview upon the observation, Staff EE, stated that: - The facility purchased laryngoscope handles and blades approximately one year ago.	L1116		

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L1116	Continued From page 15 - They were stored on the top shelf in the supply room, still in the original case. - They would never use the laryngoscope handles and blades or the ET tubes. - He did not know the facility did not have any suction tips for oral suctioning. 15. During an interview on 03/13/19 at 11:00 AM, Staff N, Clinical Quality Implementation Manager, stated that: - The only checklist for staff to validate emergency supplies was the document, "Emergency Box," which was used for the pre/post procedure monitoring area. - The facility did not have an inclusive list of unit emergency supplies and equipment. - The monitoring tool for emergency supplies, "QM Monthly Site System Review Worksheet," did not include a list of emergency supplies and was not a tool to validate staff knowledge of emergency supplies. - The facility did not have a policy that outlined the required emergency supplies to be maintained by the unit; and - The facility did not have a policy that directed staff orientation and knowledge validation for the location and use of emergency supplies.	L1116		
L1131	19 CSR 30-30.060(4)(A) Infection control standards of the facility Infection control standards of the facility must be identified in writing, in compliance with generally-agreed upon national standards such as those of the Centers for Disease Control and Prevention (CDC), Association for Professionals in Infection Control and Epidemiology (APIC), Association of peri-Operative Registered Nurses (AORN), or other standards determined	L1131		4/30/19

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L1131	Continued From page 16 acceptable by the department. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained a controlled environment to prevent cross-contamination in sterile processing and decontamination; - Staff followed acceptable sterilization standards and manufacturers instructions for use (IFU) for the monitoring of chemicals used for High-Level Disinfection (HLD) of instruments; - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for HLD of instruments; - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for steam sterilization; - Staff followed acceptable sterilization standards and facility policy for the labeling of sterile instruments and packages; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 216 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Managing Infection Prevention at Affiliates," dated 07/09/18, showed: - All staff is responsible for adhering to and incorporating infection prevention practices with service provision. - The facility uses as a reference:	L1131		

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L1131	Continued From page 17 * The Affiliate Risk Management Services infection Prevention Manual; * Centers for Disease Control and Prevention; * HealthCare Infection Control Practices Advisory Committee Guidelines; - Other resources are listed in the attachment section of this manual: * Association for the Advancement of Medical Instrumentation (AAMI); * Association of PeriOperative Registered Nurses (AORN); * Association of Professionals in Infection and Epidemiology (branch of medicine which deals with the incidence, distribution, and possible control of diseases and other factors relating to health); and * Occupational Safety and Health Administration. 2. Review of the AORN "Perioperative Standards and Recommended Practices for Instrument Cleaning," dated 2018, showed: - Recommendation V. * Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled. * Physical separation of decontamination areas (area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items) from areas where clean items are handled minimized the risk of cross-contamination. * Droplets and aerosols created during cleaning of soiled instruments can cause cross-contamination of any nearby clean items or surfaces. - Recommendation V.a. * The sterile processing area should have: - Separate clean and decontamination	L1131		

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spaces, which may be rooms or areas;
- Decontamination and clean spaces that are separated by one of three methods: A wall with a door or pass-through, a partial wall or partition that is at least 4 feet high and at least the width of the counter, or a distance of 4 feet between the instrument washing sink and the area where the instruments are prepared for sterilization.
- Recommendation VI.
* Contaminated instruments are a potential source of transmissible pathogens.

3. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed:
3.3.6.1.1 Design considerations: The decontamination area/room should be physically separate from all other processing areas and from areas in which clean or sterilization procedures are carried out, with any connecting doors and pass-through windows remaining closed.

4. Observation on 03/11/19 at 1:30 PM of the sterile processing area showed:
- The pass through window between sterile processing and decontamination was open.
- Staff F, Surgical Scrub Technician (ST, staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), was cleaning contaminated instruments in the decontamination room in direct proximity to the pass through window.
- The door to the sterile processing room was propped open.
- Two sterilizers along the wall adjacent to the

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L1131	Continued From page 19 door that protruded past the door frame and prevented the door from being closed. During an interview upon the observation, Staff A, Director of Surgical Services, stated that the sterilizers blocked the door to sterile processing from closing. 5. Observation on 03/12/19 at 9:28 AM showed the doors to sterile processing and decontamination and the pass through window were open. 6. Observation on 03/12/19 at 11:25 AM showed the door to sterile processing and the pass through window was open. 7. During an interview on 03/13/19 at 9:15 AM, Staff A stated that the door to decontamination and the pass through window were to remain closed at all times. 8. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - E.6 Quality control in chemical disinfection (chemical substances which are used to kill or deactivate pathogenic microorganisms [capable of causing illness in humans]) * Dilution and minimum effective recommendation (MEC) / minimum recommended concentration (MRC) monitoring: The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in the long-term use and reuse of a chemical disinfectant and can potentially reduce the	L1131		

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concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time.

To avoid dilution of the disinfectant, excess moisture should be removed after cleaning.

Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label.

As part of a health care facility's quality control program, Liquid Chemical Sterilants (LCS)/HLD solutions such as glutaraldehyde (Cidex OPA [brand] - high level disinfectant for semi-critical medical devices) solution should be monitored upon activation and before each use in order to detect unexpected dilution of the solution.

9. Review of the AORN "Guideline for Manual Chemical High-Level Disinfection," dated 2018, showed:
- Recommendation IV.d.
 * High-level disinfection should occur in a designated clean area that is separate from the decontamination area.
 * Separating the clean area from the area where devices are cleaned and prepared for high-level disinfection reduces the risk of device contamination that might occur when both clean and contaminated processing activities are performed in a single area.
- Recommendation VI.c.1.
 * A test strip or other Food and Drug Administration-cleared testing device specific to the disinfectant and the active ingredient in the disinfectant should be used before each use of the HLD solution.
- Recommendation VI.d.1.
 * The temperature of the HLD solution should be verified before each use with a thermometer

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calibrated within the applicable range.
- Recommendation IX:
 * Documentation should be completed to enable the identification of trends and demonstrate compliance with regulatory and accrediting agency requirements.
- Recommendation IX.a.
 * Records related to manual chemical high-level disinfection should include:
 The date and time of high-level disinfection;
 HLD solution lot number;
 HLD solution shelf-life date;
 HLD solution activation date;
 HLD solution reuse-life date;
 Results of solution test strip testing;
 Results of MRC or MEC testing, if applicable;
 HLD solution temperature;
 HLD solution exposure time;
 Quantity and description of the device or item; and
 Identity of the person performing high-level disinfection.

10. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18, showed to ensure integrity, visually inspect previously used solution before use, test and record results in appropriate testing log daily.

11. Review of the manufacturer's IFU for Cidex OPA showed:
- Reuse for Disinfection:
 * The concentration of Cidex OPA Solution during its use-life (time between activation of the solution and last date to be used) must be verified by the test strips prior to each use.
 * This is to ensure the minimum effective concentration is present.
 * Cidex OPA Solution may be used for up to a

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L1131	Continued From page 22 maximum of 14 days provided the required conditions of concentration and temperature exist. 12. Review of the facility's documents titled, "Cidex OPA Solution MEC test log showed: - The document was used to record the following information: * Date the solution was poured into the secondary container (a soaking pan); * Staff initials; * MEC test strip results; and * Comments/resolution. - Review of the monthly logs showed: * 11/18 - entries on three days; * 12/18 - entries on three days; * 01/19 - entries on four days; * 02/19 - entries on seven days; and * 03/01/19 - 03/11/19 - entries on four days: * Staff documented that the solution was changed four times in 19 weeks. - Staff failed to document: * The date and time of high-level disinfection; * HLD solution lot number; * HLD solution reuse-life date; * HLD solution exposure time; and * Quantity and description of the devices or items disinfected. 13. During an interview on 03/13/19 at 8:35 AM, Staff F stated that: - Staff checked the Cidex daily; - They only checked the Cidex on days they had procedures that required HLD. - The Cidex expired 14 days after it was mixed regardless of the MEC. - The number of HLD loads disinfected averaged between 12 and 15 HLD loads per day on procedure days.	L1131		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1131	Continued From page 23 - She did not check the Cidex MEC prior to disinfection of each load. 14. During an interview on 03/13/19 at 9:30 AM, Staff A stated that: - She did not know the Cidex MEC should be validated prior to each HLD load of instruments; and - She was not aware the time of high-level disinfection, solution lot number, reuse-life date, exposure time, quantity, and description of the device or item disinfected should be documented. 15. Review of the ANSI/ AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2018, showed: - 13.3.3 Sterilizer records * The process critical parameters (time and temperature) provided on the recording chart, printer, or tape should be reviewed, signed, and dated by the operator to indicate an acceptable cycle. * For each sterilization cycle, the following information should be recorded: (a) The load number; (b) The specific contents of the lot or load, including quantity, department, and a specific description of the items(e.g., towel packs, type/name of instrument sets); (c) The exposure time and temperature, if not provided on the sterilizer recording chart; and (d) Operator identification. 16. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18, showed: - Information that should be recorded and	L1131		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/13/2019

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REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L1131	Continued From page 24 maintained for each sterilization cycle includes guidance from Consolidated Test of American National Standard/Advancing Safety in Medical Technology: * Specific contents of the lot or load, including quantity, department, and specific description of the items (e.g. towels, type/name of instrument sets); * Exposure time and temperature, if not provided on the sterilizer recording chart; * Name or initials of operator; and * Results of biological testing, if applicable. 17. During an interview on 03/12/19 at 9:15 AM in the sterile processing room, Staff D, ST, stated that: - They did not maintain a sterilization log. - She never had any training on the sterilization process; she just continued to do what she had seen was done in the past. - She only logged sterilizer cleaning and results of the biologicals. - Each instrument package and set should be labeled with a load number and autoclave number. - She did not know they should keep a record of the content, time and temperature for each sterilizer load. 18. During an interview on 03/12/19 at 9:30 AM in the sterile processing room, Staff A stated that: - They tested the Cidex OPA solution daily. - She did not know they were supposed to test the Cidex OPA solution before every load of instruments processed. - They did not have a log to document load content, time, and temperature for the Cidex OPA solution or the steam sterilizers.	L1131		

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L1131	Continued From page 25 19. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - 13.3.1 General considerations * Each item or package intended for use as a sterile product should be labeled with a lot control identifier to allow full traceability of that item to the patient. * Each load should have a load control record that includes a detailed content list, including specific identification of sets and the contents of sealable pouches. - 13.3.2 Package labeling * Each item or package intended for use as a sterile product should be labeled with a lot control identifier prior to sterilization. The lot control identifier should identify: a) The sterilizer identification number or code; b) A detailed list of the contents (e.g., identification of multiple sets and the contents of paper-plastic pouches); c) The person who assembled the package; d) The date of sterilization; e) The cycle number (cycle run of the sterilizer); and f) The patient, if applicable. - Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for proper stock rotation. Lot identification enables personnel to retrieve items in the event of a recall and to trace problems (e.g., wet packs) to the source. Pre-sterilization labeling can be done after sterilizer and cycle assignment is determined and as the cart is loaded. Accountability to the patient and surgeon for the sterility of a reprocessed device requires documentation that can be traced to the patient.	L1131		

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L1131	Continued From page 26 Traceability is especially important as the consequences of infection can result in increased morbidity and mortality. 20. Review of the facility's policy titled, "Cleaning, Disinfection and Sterilization," dated 07/09/18, showed: - Documentation establishes accountability by documenting what instruments have been processed and provides evidence of monitoring controls for those items. * In the event of a sterilization process failure, good records will help the staff trace each package back to the event itself. * Each item or pack should be labeled with a lot identifier that designates the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). *Lot identification enables retrieval of items in the event of a recall, tracing problems to their source and facilitates proper stock rotation. 21. Observation on 03/11/19 at 3:00 PM in the sterile processing room showed 13 of 26 sterile instrument packages observed did not have a sterilizer or load number identified on the package. During an interview upon the observation, Staff O, Clinical Manager, stated that she did not know the sterilizer and load number should have been identified on the packages of sterilized instruments. Staff F stated that she did not know she was supposed to label every instrument package with the sterilizer number and load number. 22. Observation on 03/11/19 at 1:30 PM in the	L1131		

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L1131	Continued From page 27 sterile supply storage room showed: - A box of 50 infusion sets (small tubing with needle inserted into a vein for administering medication and fluid) that had expired 08/18. - Staff A removed the box of expired supplies. During an interview upon the observation, Staff A stated that Staff H, Patient Flow Coordinator and Staff T, Shipping and Receiving Coordinator, were responsible for checking for expired supplies at least monthly. 23. Observation on 03/11/19 from 1:50 PM through 2:45 PM during tour of the patient care areas, showed seven expired cans of alcohol-based hand sanitizer with expiration dates ranging from 08/18 through 12/18. 24. During an interview on 03/13/19 at 11:02 AM, Staff O stated that she did not know who was responsible to monitor the expiration dates of the alcohol-based hand sanitizer. 25. During an interview on 03/13/19 at 11:10 AM, Staff H stated that she did not know who was responsible to monitor the expiration dates of the alcohol-based hand sanitizer.	L1131		
L1146	19 CSR 30-30.060(5)(F) The facility shall follow all applicable laws The facility shall follow all applicable laws and regulations pertaining to controlled substances. This regulation is not met as evidenced by: Based on state statute, policy review, record review, and interview, the facility failed to: - Ensure controlled substance logs were maintained to include the addresses of patients	L1146		4/30/19

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L1146	Continued From page 28 who received controlled substances; and - Ensure controlled substance logs were maintained to include the reason for the destruction or wastage of controlled substances not administered. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 cases. Findings included: 1. Review of Missouri's 19 Code of State Regulations (CSR) 30-1.048(1)(3), dated 04/30/17, showed: - Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed: * The name of the substance; * Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial); * The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received; * The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or	L1146		

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L1146	Continued From page 29	L1146		

administered the substance; and
* The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.
- Individual practitioners shall maintain the records listed in subsections (1)(A)-(E) of this rule separately from patient medical records.

2. Review of Missouri's 19 CSR 30-1.078(5) showed the following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry.

3. Review of the facility's policy titled, "Policy Statement & Work Practices for Management of Controlled Substances," dated 04/30/18, showed:
- The dispensing log must include the date dispensed, patient name, patient address, drug name, strength, dosage form and quantity dispensed, and the name/initials of the person performing the dispensing.
- The chief circumstances for disposal of unwanted controlled substances are:
* The drug has been contaminated by patient contact, left over injectable drugs in a syringe, or a tablet that has fallen out of a patient's hand or mouth. In these cases the drug may be destroyed by two employees. The drug must be destroyed beyond reclamation and documented

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L1146	Continued From page 30 as described below. * When practitioners administer injectable controlled substances, there will be a small amount remaining in the hub of the syringe. These are considered insignificant in the course of normal practice. These amounts are not considered lost. They should be documented on the logs so they are accounted for and records balance. (Note: The facility did not include documenting the reason for wastage in their list of required documentation.) 4. Review of the facility's documents titled, "Controlled Substance Dispensing Or Administration Log," dated 01/30/19 through 03/13/19, showed: - Staff did not include the patients' addresses on the log; and - Staff did not document the reason controlled substances were wasted. 5. During an interview on 03/12/19 at 9:00 AM, Staff B, Registered Nurse, stated that: - They did not document the patient's address on the "Controlled Substance Dispensing Or Administration Log;" and - Staff did not document the reason controlled substances were wasted unless the reason for wastage was something "weird."	L1146		

Missouri Department of Health and Senior Services

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/11/19 to 03/13/19 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Reproductive Health Services of Planned Parenthood	Survey Exit Date	3/13/19
Facility Address/ City/Zip	4251 Forest Park Avenue, St. Louis, MO 63108	Statement of Deficiencies (SOD): L-tags	L-1076, L-1103, L-1131

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction. Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. **(TAG):**
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc.).

   B. **(CORRECTIVE ACTION):**
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. **(WHEN):**
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. **(WHO):**
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. **(MONITORING AND/OR TRACKING PROCEDURES):**
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. **EVIDENCE/EXHIBIT ATTACHMENTS(s).** If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L-1076 & L-1103	On May 20, 2019, RHS received a letter responding to the Plan of Correction it timely submitted on April 9, 2019, in response to the Statement of Deficiencies issued by the Department on March 25, 2019. The Department's May 20 letter seeks additional clarification or information regarding RHS's Plan of Correction of three cited deficiencies. RHS appreciates this opportunity to provide additional clarification and/or information on these three deficiencies, and understands its Plan of Correction of all other deficiencies identified in the Statement of Deficiency to be acceptable to the Department. As the Department is aware, our license is scheduled to expire on May 31, 2019, and RHS has been endeavoring in good faith to resolve the issues raised by the Department, including by making multiple physicians available for interviews, providing patient records, and otherwise complying with the Department's investigation. RHS once again asks the Department to renew its license prior to the May 31 expiration date, and to respond to this amended Plan of Corrections by Friday, May 24. RHS takes our responsibility to provide the best possible care for our patients very seriously. We are committed to			See column B (CORRECTIVE ACTION)	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
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	the highest medical, legal, and ethical standards. The health and safety of our patients is our top priority. Ensuring the health and safety of our patients is central to our mission and fundamental to every person who works at RHS. RHS adheres to the highest standards, and we take swift action to correct any deficiency if we ever discover that these standards are not being met. As a high-quality health care provider, we constantly strive to improve, and we welcome all opportunities to do so. We always cooperate fully with all Department inspections and quickly address any issues that officials share with us. And we are committed to doing so in the future, because we are committed to our patients and providing them the best care. Under section 188.027.6 RSMo., "[t]he physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of" the information required in the statute. As RHS observed in the April Plan of Correction, with regard to the two patients identified (#7 and #10), the physician who consented the patient also provided the procedure to the patient. The Department's May 20 letter appears to acknowledge that there is no deficiency with				

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	regard to these two patients. Nevertheless, the Department references unspecified "additional instances" in which the physician providing the state-mandated information "differed" from the physician who provided the abortion. But in the very next sentence, the letter states that the Department has "been unable to verify the fact or extent of your compliance." Moreover, the Department expresses concern that a supervising physician who "is merely present in the building without taking any active role in perform or inducing the abortion" is not a physician who performs or induces an abortion within the meaning of section 188.027.6. As RHS noted in its Plan of Correction, the Department advised the Circuit Court of Jackson County in its legal filings that "[w]hen there are two or more physicians who are substantially involved in performing or inducing the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 16, 2017). Additionally, as the circuit court found, under the Department's reading of the statute, "when multiple doctors are involved in the continuum of care before, during, and after a procedure that anyone of those physicians could provide the required information." Order				

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	at 6, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 23, 2017). We believe that attending physicians at RHS have been substantially involved in a patient's care, including when a fellow or resident is being trained to provide abortions and throughout each patient's care, and consistent with how physician supervision is understood to function in the context of residency and fellowship regardless of specialty or type of procedure, and therefore, RHS's practices have been fully compliant with the statute, the Department's direction and the Court's order. RHS, however, desires to resolve this issue promptly. To that end, and to ensure Missourians can continue accessing abortion in their home state, RHS will revise its policies to require that when a fellow or resident is providing a procedure under supervision, the supervising physician will provide the state-mandated information required by section 188.027.6, RSMo., at least 72 hours prior and will be physically present in the procedure room during the abortion procedure. Your rejection letter states, inaccurately, that the regulation requires that "[a] pelvic examination must be completed prior to every abortion for the purpose of '*determining the duration of gestation, identifying*				

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	preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management."" 19 CSR 30-30.060(2)(D) (emphasis supplied). In fact, that regulation provides in full: A written medical history shall be obtained for each patient. **A health assessment including a pelvic examination shall be performed.** Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. (Emphasis added.) The regulation does not specify the time when a pelvic exam must be performed, except that it must be performed before the abortion procedure. The letter states that "[i]nspectors found that pelvic examinations were performed immediately prior to the actual abortion procedure," which the Department now believes is not compliant with the regulation. This change in position is surprising because it has long				

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	been RHS's practice to perform a pelvic examination in the context of surgical abortion on the day of the procedure, which is when it is medically appropriate and clinically relevant. And although the Department has inspected RHS annually for many years, it has never suggested that the examination be performed at a different time. This change is especially surprising because just last year, RHS's practices with respect to pelvic examinations were a focus of the Department's inspection. Specifically, last year the Department cited RHS for failing to ensure a pelvic exam was completed prior to a medication abortion. See Statement of Deficiency (survey date March 7, 2018). This "deficiency" was already an alteration of the Department's prior understanding of this regulation, because, as the Department is aware, prior to last year, the Department did not enforce the pelvic exam requirement for medication abortion because the requirement was written before approval of medication abortion in the United States, and it is medically unnecessary for that method of abortion. Because the Department changed its interpretation of this regulation last year and now requires a pelvic exam prior to medication abortion, and because RHS's physicians are not willing to impose on patients an invasive exam that is not medically appropriate in the context of medication abortion, we currently are not providing medication abortion to patients in Missouri.				

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	Most relevantly here, however, in multiple exchanges with RHS over the supposed deficiency for not providing a pelvic exam prior to a medication abortion, the Department at no point indicated when this exam would have to be performed other than prior to the abortion procedure (in either the medication or surgical abortion context). In now taking the position that the pelvic exam cannot be performed on the day of the abortion, the Department has expressed the concern that this timing "does not "meet[] the purpose of the requirement, which … includes 'detecting factors which could influence the choice of the procedure.'" This concern is unwarranted. Putting aside that as a result of the medically unnecessary pelvic requirement medication abortion is not available in Missouri (and at any rate is not an option after 10 weeks in pregnancy), a patient and physician can change the abortion method at any time prior to the abortion, in the exceedingly unlikely scenario that a pelvic exam reveals a reason to do so. At any rate, the primary information needed in determining the options that may be available to the patient is gestational age, which in current practice is determined not by a pelvic exam but by an ultrasound examination and medical history. In addition to				

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	gynecologic visits. ACOG Committee Opin. No. 754 (Oct. 2018), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/The-Utility-of-and-Indications-for-Routine-Pelvic-Examination. Minimizing the number of pelvic exams, specifically restricting them to instances in which there is clear medical benefit, is important for all patients but especially for those who find vaginal exams particularly distressing, including because they have experienced sexual or other trauma. Although RHS believes its existing practices are consistent with the regulation and with good patient care, RHS desires to resolve this issue promptly. To that end, and to ensure Missourians can continue accessing abortion in their home state, RHS will revise its policies to require that a pelvic exam must be performed on the same day the patient receives the state-mandated information, at least 72 hours before the abortion. RHS notes that forcing patients to receive a pelvic exam on the same day she receives the state-mandated information will result in the patient receiving two pelvic exams, because as discussed above, the pelvic exam is needed immediately prior to the abortion to ascertain factors that could influence how the procedure should be performed. RHS will advise all patients that the first exam is medically unnecessary but required by the State of				

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	Missouri. Finally, the rejection letter states that RHS's policy with regard to the pelvic exam and medication abortion does not comply with the regulation, because the policy states that a pelvic exam would be performed before a medication abortion "when indicated (e.g., vaginal bleeding, or abdominal/pelvic pain, *or as required by Missouri regulation*)." (Emphasis added.) As the policy clearly states, and as RHS stated last year to the Department, a pelvic exam will be performed "as required by Missouri regulation." The Department interprets this statement as "suggest[ing] that there may be times when a pelvic examination would not be required by Missouri regulations." This is not the intent of the policy, and RHS will revise its policy to state: "As required by Missouri regulation, a pelvic exam must be completed before a medication abortion." The Department's letter states that it "cannot complete our investigation until it interviews the physicians involved in the care provided in the potential deficient practices … at the facility," and that the "investigation needs to be completed and any deficiencies resolved before the expiration of RHS's license on May 31, 2019."				

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	As the Department is aware, all care at RHS is supervised by an attending physician. The Department has asked to interview two of the RHS attending physicians: Dr. Eisenberg who is a co-medical director, and Dr. McNicholas. Although those physicians are not RHS employees, their counsel offered to make them available for interviews, but the Department rejected that offer. It is, therefore, not true that the Department is unable to interview the physicians involved in the care the Department is investigating. Rather, the Department has stated that it will not proceed with any further interviews unless they are in a specified order. This is contrary to the way the Department previously proceeded with this investigation, as on April 11, the Department asked to interview 8 individuals (7 physician and 1 registered nurse), and then proceeded to interview that nurse—the only person identified who is an RHS employee, and who RHS accordingly was able to produce promptly for an interview, despite that she was listed seventh on the Department's list. It was only on May 15 that the Department said it would not interview the attending physicians because interviews needed to be conducted in a specific order. Those physicians remain willing to talk to the Department, and RHS urges the Department to interview them. Again, as supervising physicians, these physicians were responsible				

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	for the care provided at RHS, and it is unreasonable to refuse to proceed with the investigation by not speaking with them. This is especially true because, as the Department is well aware, the physicians whose counsel have declined for them to be interviewed are not RHS employees, and therefore, we are unable to compel them to sit for an interview—particularly a free-ranging interview and under circumstances in which the Department has indicated it could make criminal referrals or referrals to the board of registration for the healing art. And this demand is even more unreasonable as to the Barnes Jewish hospital residents, who have not provided care at RHS since September 2018, when their clinical rotation at RHS ended. Finally, we note that the letter states that the Department has identified potential deficiencies, and included among them are those issues discussed in the letter and addressed above. As RHS has previously offered, RHS is willing to answer any questions the Department may have, including addressing any potential deficient practice if the Department will identify those issues. This is what § 197.293, RSMo., contemplates: a back and forth in which the Department identifies any issues with compliance and Planned Parenthood then outlines what action it will take to bring its practices in line with the Department's view—and this is precisely what we have done with the above issues and would do for any of the potential deficiencies.				

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	For these reasons and because the Department's refusal to proceed with its investigation in a reasonable manner threatens to close the sole remaining abortion provider in the state, thereby denying Missouri women their constitutional right to abortion, RHS respectfully requests the Department to reconsider its position—for the benefit of the Missourians it is supposed to serve.				
L-1131	Provide more specific information regarding the frequency and type of audits that will be completed to ensure compliance is maintained.	4/30/19	Director of Surgical Services & CQI Manager	2019 Tag L1131 Audit to be completed weekly for 4 weeks, monthly for 5 months and once more after a year to report that tagged items remain compliant. The Infection Prevention Audit completed on a monthly basis includes as one of its checks: Check documentation for HDL Log completed prior per use.	L1131 Audit Infection Prevention Audit

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/13/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/11/19 to 03/13/19 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Reproductive Health Services of Planned Parenthood	Survey Exit Date	3/13/19
Facility Address/ City/Zip	4251 Forest Park Avenue, St. Louis, MO 63108	Statement of Deficiencies (SOD): L-tags	L-1076, L-1103, L-1131

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction. Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for every citation.

   A. **(TAG):**
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc.).

   B. **(CORRECTIVE ACTION):**
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. **(WHEN):**
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. **(WHO):**
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. **(MONITORING AND/OR TRACKING PROCEDURES):**
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. **EVIDENCE/EXHIBIT ATTACHMENTS(s).** If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

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L-1076 & L-1103	On May 20, 2019, RHS received a letter responding to the Plan of Correction it timely submitted on April 9, 2019, in response to the Statement of Deficiencies issued by the Department on March 25, 2019. The Department's May 20 letter seeks additional clarification or information regarding RHS's Plan of Correction of three cited deficiencies. RHS appreciates this opportunity to provide additional clarification and/or information on these three deficiencies, and understands its Plan of Correction of all other deficiencies identified in the Statement of Deficiency to be acceptable to the Department. As the Department is aware, our license is scheduled to expire on May 31, 2019, and RHS has been endeavoring in good faith to resolve the issues raised by the Department, including by making multiple physicians available for interviews, providing patient records, and otherwise complying with the Department's investigation. RHS once again asks the Department to renew its license prior to the May 31 expiration date, and to respond to this amended Plan of Corrections by Friday, May 24. RHS takes our responsibility to provide the best possible care for our patients very seriously. We are committed to			See column B (CORRECTIVE ACTION)	N/A

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	the highest medical, legal, and ethical standards. The health and safety of our patients is our top priority. Ensuring the health and safety of our patients is central to our mission and fundamental to every person who works at RHS. RHS adheres to the highest standards, and we take swift action to correct any deficiency if we ever discover that these standards are not being met. As a high-quality health care provider, we constantly strive to improve, and we welcome all opportunities to do so. We always cooperate fully with all Department inspections and quickly address any issues that officials share with us. And we are committed to doing so in the future, because we are committed to our patients and providing them the best care. Under section 188.027.6 RSMo., "[t]he physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of" the information required in the statute. As RHS observed in the April Plan of Correction, with regard to the two patients identified (#7 and #10), the physician who consented the patient also provided the procedure to the patient. The Department's May 20 letter appears to acknowledge that there is no deficiency with				

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	regard to these two patients. Nevertheless, the Department references unspecified "additional instances" in which the physician providing the state-mandated information "differed" from the physician who provided the abortion. But in the very next sentence, the letter states that the Department has "been unable to verify the fact or extent of your compliance." Moreover, the Department expresses concern that a supervising physician who "is merely present in the building without taking any active role in perform or inducing the abortion" is not a physician who performs or induces an abortion within the meaning of section 188.027.6. As RHS noted in its Plan of Correction, the Department advised the Circuit Court of Jackson County in its legal filings that "[w]hen there are two or more physicians who are substantially involved in performing or inducing the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 16, 2017). Additionally, as the circuit court found, under the Department's reading of the statute, "when multiple doctors are involved in the continuum of care before, during, and after a procedure that anyone of those physicians could provide the required information." Order				

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	at 6, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 23, 2017). We believe that attending physicians at RHS have been substantially involved in a patient's care, including when a fellow or resident is being trained to provide abortions and throughout each patient's care, and consistent with how physician supervision is understood to function in the context of residency and fellowship regardless of specialty or type of procedure, and therefore, RHS's practices have been fully compliant with the statute, the Department's direction and the Court's order. RHS, however, desires to resolve this issue promptly. To that end, and to ensure Missourians can continue accessing abortion in their home state, RHS will revise its policies to require that when a fellow or resident is providing a procedure under supervision, the supervising physician will provide the state-mandated information required by section 188.027.6, RSMo., at least 72 hours prior and will be physically present in the procedure room during the abortion procedure. Your rejection letter states, inaccurately, that the regulation requires that "[a] pelvic examination must be completed prior to every abortion for the purpose of *determining the duration of gestation, identifying*				

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	preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management."" 19 CSR 30-30.060(2)(D) (emphasis supplied). In fact, that regulation provides in full: A written medical history shall be obtained for each patient. **A health assessment including a pelvic examination shall be performed.** Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. (Emphasis added.) The regulation does not specify the time when a pelvic exam must be performed, except that it must be performed before the abortion procedure. The letter states that "[i]nspectors found that pelvic examinations were performed immediately prior to the actual abortion procedure," which the Department now believes is not compliant with the regulation. This change in position is surprising because it has long				

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	been RHS's practice to perform a pelvic examination in the context of surgical abortion on the day of the procedure, which is when it is medically appropriate and clinically relevant. And although the Department has inspected RHS annually for many years, it has never suggested that the examination be performed at a different time. This change is especially surprising because just last year, RHS's practices with respect to pelvic examinations were a focus of the Department's inspection. Specifically, last year the Department cited RHS for failing to ensure a pelvic exam was completed prior to a medication abortion. See Statement of Deficiency (survey date March 7, 2018). This "deficiency" was already an alteration of the Department's prior understanding of this regulation, because, as the Department is aware, prior to last year, the Department did not enforce the pelvic exam requirement for medication abortion because the requirement was written before approval of medication abortion in the United States, and it is medically unnecessary for that method of abortion. Because the Department changed its interpretation of this regulation last year and now requires a pelvic exam prior to medication abortion, and because RHS's physicians are not willing to impose on patients an invasive exam that is not medically appropriate in the context of medication abortion, we currently are not providing medication abortion to patients in Missouri.				

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	Missouri. Finally, the rejection letter states that RHS's policy with regard to the pelvic exam and medication abortion does not comply with the regulation, because the policy states that a pelvic exam would be performed before a medication abortion "when indicated (e.g., vaginal bleeding, or abdominal/pelvic pain, *or as required by Missouri regulation*)." (Emphasis added.) As the policy clearly states, and as RHS stated last year to the Department, a pelvic exam will be performed "as required by Missouri regulation." The Department interprets this statement as "suggest[ing] that there may be times when a pelvic examination would not be required by Missouri regulations." This is not the intent of the policy, and RHS will revise its policy to state: "As required by Missouri regulation, a pelvic exam must be completed before a medication abortion." The Department's letter states that it "cannot complete our investigation until it interviews the physicians involved in the care provided in the potential deficient practices … at the facility," and that the "investigation needs to be completed and any deficiencies resolved before the expiration of RHS's license on May 31, 2019."				

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	As the Department is aware, all care at RHS is supervised by an attending physician. The Department has asked to interview two of the RHS attending physicians: Dr. Eisenberg who is a co-medical director, and Dr. McNicholas. Although those physicians are not RHS employees, their counsel offered to make them available for interviews, but the Department rejected that offer. It is, therefore, not true that the Department is unable to interview the physicians involved in the care the Department is investigating. Rather, the Department has stated that it will not proceed with any further interviews unless they are in a specified order. This is contrary to the way the Department previously proceeded with this investigation, as on April 11, the Department asked to interview 8 individuals (7 physician and 1 registered nurse), and then proceeded to interview that nurse—the only person identified who is an RHS employee, and who RHS accordingly was able to produce promptly for an interview, despite that she was listed seventh on the Department's list. It was only on May 15 that the Department said it would not interview the attending physicians because interviews needed to be conducted in a specific order. Those physicians remain willing to talk to the Department, and RHS urges the Department to interview them. Again, as supervising physicians, these physicians were responsible				

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	for the care provided at RHS, and it is unreasonable to refuse to proceed with the investigation by not speaking with them. This is especially true because, as the Department is well aware, the physicians whose counsel have declined for them to be interviewed are not RHS employees, and therefore, we are unable to compel them to sit for an interview—particularly a free-ranging interview and under circumstances in which the Department has indicated it could make criminal referrals or referrals to the board of registration for the healing art. And this demand is even more unreasonable as to the Barnes Jewish hospital residents, who have not provided care at RHS since September 2018, when their clinical rotation at RHS ended. Finally, we note that the letter states that the Department has identified potential deficiencies, and included among them are those issues discussed in the letter and addressed above. As RHS has previously offered, RHS is willing to answer any questions the Department may have, including addressing any potential deficient practice if the Department will identify those issues. This is what § 197.293, RSMo., contemplates: a back and forth in which the Department identifies any issues with compliance and Planned Parenthood then outlines what action it will take to bring its practices in line with the Department's view—and this is precisely what we have done with the above issues and would do for any of the potential deficiencies.				

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	For these reasons and because the Department's refusal to proceed with its investigation in a reasonable manner threatens to close the sole remaining abortion provider in the state, thereby denying Missouri women their constitutional right to abortion, RHS respectfully requests the Department to reconsider its position—for the benefit of the Missourians it is supposed to serve.				
L-1131	Provide more specific information regarding the frequency and type of audits that will be completed to ensure compliance is maintained.	4/30/19	Director of Surgical Services & CQI Manager	2019 Tag L1131 Audit to be completed weekly for 4 weeks, monthly for 5 months and once more after a year to report that tagged items remain compliant. The Infection Prevention Audit completed on a monthly basis includes as one of its checks: Check documentation for HDL Log completed prior per use.	L1131 Audit Infection Prevention Audit

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711
Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

May 23, 2019

Cathy Williams, Interim President & CEO
Reproductive Health Services of Planned Parenthood
425 Forest Park Avenue
St. Louis, MO 63108

Re: Response to Revised Plan of Correction

Dear Ms. Williams:

We are in receipt of your revised Plan of Correction, dated yesterday, regarding the ongoing deficiencies noted in our letter of May 20, 2019. The Department accepts the revised Plan of Correction in reference to the deficiency identified in L-1103 regarding pelvic examinations not being performed at a time that could influence the choice of the procedure on the condition that the proposed change is implemented immediately and monitoring of ongoing continued compliance with this requirement is also implemented immediately. The Department also accepts the revised Plan of Correction in reference to the deficiency identified in L-1131 regarding infection-control standards. However, your response fails to address continuing concerns regarding quality of care, standard of care, and statutory and regulatory compliance. These continuing concerns include, but are not necessarily limited to, the following:

First, your proposed Plan of Correction regarding compliance with the same-physician requirement of Missouri's informed consent law fails to comport with the requirements of that statute. The statute provides that "the physician who is to *perform or induce* the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of . . . [ ]" the immediate and long-term medical risks to the woman as specified in the statute. § 188.027.6, RSMo (emphasis added). Under the statute, the physician who performs the physician portion of the informed consent must be the same physician who "performs or induces" the abortion. Your response contends that the Circuit Court of Jackson County stated that, under the State's interpretation of the statute, "when multiple doctors are involved in *the continuum of care* before, during, and after a procedure that any one of those physicians could provide the required information." May 22 POC, at 5 (quoting Judgment/Order at 6, in Case No. 1716-CV24109 (Oct. 16, 2017)) (emphasis added). Respectfully, to the extent that the Circuit Court was attributing this interpretation to the State, it misconstrued the State's position, which is set forth in our brief in that case (which you also quote): "When there are two or more physicians who are substantially involved in *performing or inducing* the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." May 22 POC, at 5. Moreover, your Plan of Correction fails to note that the Circuit Court explicitly rejected the interpretation on which you now rely. In the same paragraph you quote, the Court stated that this interpretation "expands the language of subsection 6 beyond its written words." In other words, the interpretation on which you now rely was never advanced by the State and was rejected by the Circuit Court. Under the statute, where two or more physicians are involved in performing or inducing an abortion, the informed-consent process must

be performed by a physician who is actively involved in "performing or inducing" the abortion, not merely (as your response indicates) "substantially involved in a patient's care." Thus, your proposed revision to address this issue—*i.e.*, to require that the physician who performed the informed consent process must be "physically present" during the abortion procedure—is insufficient. To "perform or induce" the abortion under the statute, the physician who performed the informed consent process, at the very least, must play a substantial and active role in performing or inducing the abortion—mere physical presence is not enough. Contrary to your response, moreover, our May 20 letter did not acknowledge that there were no deficiencies with regard to Patient #7 and Patient #10. We acknowledged in the letter that your proposed Plan of Correction characterized the supervising physicians as actively participating in inducing the abortions for these patients. However, we specifically noted that we have been unable to verify the extent of your compliance with this requirement given that several physicians have refused to participate in interviews and that the Plan of Correction failed to provide adequate assurance of compliance and identify the systemic changes necessary to assure that the deficient practice would not recur.

In addition, the continued refusal of several physicians to cooperate in interviews regarding our ongoing complaint investigation obstructs our ability to verify that your facility "is in compliance with all requirements of applicable statutes and regulations," as required before a license can be renewed under 19 CSR 30-30.050(2)(I). Previously, we have requested that seven physicians who have provided patient care at your facility participate in interviews regarding medical records retrieved from your facility during the complaint investigation. Five of those physicians have refused to participate in interviews at all. Three of those five physicians who have refused to participate in interviews are not residents, but fully qualified physicians who have an ongoing professional relationship with your facility. You have taken the position that you lack authority to compel these physicians to participate in interviews because they are independent contractors, not employees. But it is the duty and responsibility of your facility to cooperate and ensure that all physicians who provide patient care at your facility are available for interviews during the Department's investigation. The physicians' refusal to cooperate in interviews is unprecedented and departs from longstanding practice at your facility and virtually every other regulated facility. And you have provided no clear indication of what steps you have taken, if any, to secure the cooperation of these physicians.

Instead, you have offered to produce for interviews two attending physicians, Dr. Eisenberg and Dr. McNicholas, on the ground that they supervised the care provided by the other physicians that the Department is seeking to interview. As I have repeatedly advised RHS, interviewing the attending or supervising physicians before interviewing the physicians who actually provided patient care contradicts well-established investigative standards that we apply in all investigations. Investigative standards dictate that the individuals directly involved in patient care should be interviewed first, followed by interviews of supervisors or managers with less direct involvement in the incidents being reviewed. By requesting that we interview the attending physicians before we have been able to interview the other five physicians, you are effectively requesting special treatment, and a departure from well-established investigative practices that we apply to other facilities in similar investigations.

That said, in the interest of achieving a resolution of these issues as quickly as possible, we are willing to interview Dr. McNicholas and Dr. Eisenberg immediately, as early as tomorrow morning, May 24. To be clear, we are agreeing to interview the attending physicians out of order under protest, emphasizing

that this is a departure from investigative practices followed in similar investigations at other facilities. And we emphasize that we are ***not*** withdrawing our request to interview the other five physicians whom we have requested for interviews. In addition to producing Dr. McNicholas and Dr. Eisenberg, we also require that you make the other requested physicians available—especially the three fully qualified physicians who have an ongoing professional relationship with your facility—without any further delay. As noted in my May 20 letter, our complaint investigation has identified a large number of potential deficient practices requiring explanation by the physicians directly involved in patient care, as well as the attending physicians. Moreover, we reserve the right to seek follow-up interviews with Dr. McNicholas and Dr. Eisenberg in the event that we have additional questions following the interviews of the other physicians.

Please respond promptly with the availability of Dr. McNicholas and Dr. Eisenberg for interview.

Sincerely,

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services

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L 000	Initial Comments An on-site, unannounced state complaint investigation (MO00154375) was conducted from April 2, 2019, to May 28, 2019, in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). The complaint investigation was unable to be completed, due to RHS' refusal to fully cooperate with an ongoing investigation. To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews and requests for copies of patient medical records and relevant policies were initially refused. Requested records have been subsequently provided. Investigation findings include: RHS violated applicable regulation, 19 CSR 30-30.060(1)(A)(8) and state law evidenced by a failure to: -ensure the Department of Health and Senior Services was able to complete an investigation, as required by Chapter 197.230 RSMo, to include failing to induce, encourage, compel, or motivate the physicians who provide patient care at RHS to submit to interviews and failure to ensure the collection of relevant medical records; -ensure the physician performing the informed consent was the same physician performing the abortion, for 8 patients, as required by Chapter 188.027.6 RSMo; -ensure a complication report was completed and filed for a failed abortion for 1 patient, as required by Chapter 188.052.2 RSMo. RHS violated applicable regulation, 19 CSR	L 000		

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L 000	Continued From page 1 30-30.060(1)(A)(1) pertaining to providing care in a safe environment and following standards of care, evidenced by a failure to: -ensure the pelvic examination was completed at the time of the health assessment and in a manner to accurately document the size and orientation of 1 patient's uterus prior to a surgical abortion, which contributed to a failed abortion; -ensure the accuracy of a gross examination of fetal tissue to ensure a completed abortion for 2 patients; -ensure there was communication with the pathology lab after the discovery of failed abortions for 2 patients; -ensure prompt follow up with a patient complaining of continuing pregnancy symptoms for 1 patient; -ensure informed consent was provided to 2 patients prior to the performance of new surgical abortions following failed abortions; -ensure the informed consent process included the seventy-two (72) hour required waiting period for 2 patients; -ensure the appropriateness of nursing care for 1 patient who was instructed to perform a self-fundal massage for post-abortion care at 7 weeks and 1 day gestational age; -ensure an abortion was planned in a safe environment for 1 patient presenting for a therapeutic abortion at 21 weeks and 5 days with a previous history of a C-section and a diagnosis of placenta previa, resulting in an emergency transfer to a hospital, where the patient was described as critically ill and suffering from shock, on pressors (drug for treating hypotension) and suffering massive blood loss. The patient underwent emergency surgery (bilateral uterine artery embolization) to control life-threatening blood loss (2L);	L 000		

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L 000	Continued From page 2 -ensure the appropriate risks and benefits were conveyed to 1 patient of the likelihood of a diagnosis of placenta accreta (a serious pregnancy condition that occurs when the placenta grows too deeply into the uterine wall) at 21 weeks and at term with an ultrasound not showing evidence of an accreta. RHS violated applicable regulation, 19 CSR 30-30.060(3)(B), pertaining to the accuracy of patient medical records, evidenced by a failure to: -ensure medical records were maintained in a manner that accurately documents the time and date a record was created or amended and any specific amendments made to the record; -ensure the medical record accurately identified the identity of the physician inducing a medication abortion for 1 record; -ensure the medical record accurately documents a record of supervision for residents and fellows performing abortions at the facility for 2 records. RHS violated applicable regulation, 19 CSR 30-30.060(3)(H) pertaining to the submission of complication reports, evidenced by a failure to: -ensure a complication report for 1 failed medication abortion was submitted to the department, as required. RHS violated applicable regulation, 19 CSR 30-30.060(8)(C) pertaining to the lack of action taken regarding identified problems with care provided, evidenced by a failure to: - ensure the appropriateness of the care provided at the facility was reviewed regarding the occurrence of 3 failed abortions documented within the medical records from [redacted]	L 000		

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L 000	Continued From page 3 through [redacted] -ensure that action was taken regarding problems identified in the medical care provided at the facility, regarding the failed abortions. (Note: The Statement of Deficiencies issued to RHS pursuant to the March 13, 2019 annual inspection showed violations of 19 CSR 30-30.060(D) (L1103) for failure to perform a pelvic examination during the 72-hour preoperative assessment and 19 CSR 30-30.060(1)(A)(8) (L1076) for failure of the facility to ensure the same physician performing the informed consent performs the abortion.)	L 000		
L1069	19 CSR 30-30.060(1)(A)(1) The governing body shall have full legal The governing body shall have full legal responsibility for determining, implementing, and monitoring policies governing a facility's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment and in accordance with all legal requirements and standards of care. This regulation is not met as evidenced by: Based on facility record review and review of the standards of medical care, the facility failed to ensure: -the pelvic examination was completed at the time of the health assessment and in a manner to accurately document the size and orientation of 1 patient's (Patient #1) uterus prior to a surgical abortion, which contributed to a failed abortion; -the accuracy of a gross examination of fetal tissue to ensure a completed abortion for 2	L1069		

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L1069	Continued From page 4	L1069		

patients (Patient #2 and #3);
-there was communication with the pathology lab after the discovery of failed abortions for 2 patients (Patient #2 and #3);
-the prompt follow up with a patient complaining of continuing pregnancy symptoms for 1 patient (Patient #2);
-informed consent was provided to 2 patients (Patient #2 and #3) prior to the performance of new surgical abortions following failed abortions;
-the informed consent process included the seventy-two (72) hour required waiting period for 2 patients (Patient #2 and #3);
-the appropriateness of nursing care for 1 patient (Patient #4) who was instructed to perform a self-fundal massage for post-abortion care at 7 weeks and 1 day gestational age;
-an abortion was planned in a safe environment for 1 patient (Patient #12) presenting for a therapeutic abortion at 21 weeks and 5 days with a previous history of a C-section and a diagnosis of placenta previa, resulting in an emergency transfer to a hospital, where the patient was described as critically ill and suffering from shock, on pressors (drug for treating hypotension) and suffering massive blood loss. The patient underwent emergency surgery (bilateral uterine artery embolization) to control life-threatening blood loss (2L);
-the appropriate risks and benefits were conveyed to 1 patient (Patient #12) of the likelihood of a diagnosis of placenta accreta (a serious pregnancy condition that occurs when the placenta grows too deeply into the uterine wall) at 21 weeks and at term with an ultrasound not showing evidence of an accreta.

Findings included:

1. Review of the medical record for Patient #1

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L1069	Continued From page 5 showed she presented to RHS on [redacted], to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. The document is dated [redacted]. A transabdominal ultrasound was performed on the patient and gestational age was determined to be 7 weeks and 4 days. The patient agreed to have a vacuum aspiration. The record notes the patient underwent a prior surgical abortion in 2016 and encountered "abnormal bleeding after abortion" as a result of that event. Patient #1 presented to RHS for a surgical abortion on [redacted]. A physical and pelvic examination is documented in the record as conducted by physician resident, Staff F. Staff F documented the uterine orientation as "Ant" and the uterine size as "less than 6 weeks". The procedure was performed at 11:35 a.m. by physician fellow, Staff A. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated [redacted], at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated [redacted] at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The recorded	L1069		

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L1069	Continued From page 6 entry was made by Staff J, nurse. The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated [redacted] at 12:00p.m. An additional note in the [redacted] record states, "Pt had unsuccessful in clinic procedure. Medication AB initiated. HCG drawn. Pt scheduled for apt for [redacted] for repeat HCG." The entry was made by Staff J, nurse. An untitled document, referenced to patient #1, generated by Staff E, dated [redacted], at 9:20 a.m., states in part, "Supervising provider review for encounter on [redacted] 9:20 AM I was present for the procedure and agree with the treatment and follow up plan(s)." Further, the document noted, "pt. with an very acutely retroflexed uterus and the pregnancy at the fundus. Although the canal and path was able to be appreciated with eth17F Pratt dilator, the angle and traction on the cervix was quite uncomfortable for the patient. The position of the uterus made TA u/S ineffective. TV U/S was able to confirm the path, but given the unique position of the uterus and pts discomfort, coupled with early gestational age, we opted to stop the Sab and proceed with MAB. Discussed and explained with patient. Questions answered." The record indicates Patient #1 contacted RHS on [redacted] at 12:05 p.m., and spoke to Staff J, nurse. The record documents the patient contact as follows, "Spoke with pt who reports only mild cramping and scant bleeding since taking misoprostol at 530pm last evening. Encouraged pt to wait thru tonight to give misoprostol the full 24 hrs to work and if she still thinks she has not passed the pregnancy tomorrow morning to return to clinic. Pt	L1069		

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L1069	Continued From page 7 verbalized an understanding of plan and states she will comply. [Staff E] aware and agrees with plan." Patient #1 presented to RHS on [redacted], for post-abortion care. The record, dated [redacted], documents an ultrasound conducted by physician, Staff M. The fetal gestational age was found to be 9 weeks and 0 days. Findings included are identified as, "yolk sac, cardiac motion, fetal pole, gestational sac with double ring sign, single". Staff E performed a physical examination on Patient #1 and determined the uterine orientation to be "post" and a uterine size of "9-10 weeks". (This finding is inconsistent with the findings of Staff F on [redacted].) The visit comment in the record states, "Pt reutrned [sic] to clinic with continuing pregnancy confirmed on sono. Pt desires to have evacuation today if possible. Pt reports only spotting and mild cramping after taking misoprostol at home at 530pm on [redacted] (more than 24 hrs ago). Discussed with [Staff E] who ordered pt receive misoprostol and IV sedation and will attempt in clinic procedure. Discussed with pt who is in agreement. The visit comment is recorded by Staff J, nurse at 11:00 a.m. on [redacted]. The procedure was performed at 12:56 p.m. by Staff E. The abortion was performed under ultrasound. The patient's cervix was dilated to 25 and a 9mm cannula was used for the aspiration. The physician notes that the procedure was completed without difficulty [sic]. An additional comment in the record, dated [redacted], 1:05 p.m., from an unknown author, states, "S/p failed Sab 2/2 dicomfotr [sic]and uterune [sic] position. Attempted MAB without success. USe of IVS and U/S guidance was able to evacuate without diffciluty [sic]. Extremely RV and Retroflexed".	L1069		

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L1069	Continued From page 8 On May 28, 2019, Staff E was interviewed. When asked if she was present during the pelvic examination conducted on Patient #1 by Staff F, Staff E stated, "I don't know." When asked about the difference between the results of the pelvic examination conducted on [redacted], by Staff F, and the pelvic examination conducted by her on [redacted], she stated, "Female anatomy can change from day to day. In addition, there were several weeks between, or there was some time between the first and the second, in which the pregnancy was continuing to grow. One of the biggest drivers of change in female anatomy is change in the size of uterus. So, as the pregnancy grows, the uterus changes size ....In addition, this patient did receive medication in between, which changes both the architecture and the size direction of the uterus". The Department finds this explanation is insufficient to satisfy compliance with this requirement. On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the supervising physician follow up with a resident who was found to have conducted or documented a pelvic examination inaccurately, he stated, "The residents are not providing the care, because they are not providing the care without that physician present." He stated that the residents never document care that is provided. He further stated, "We are documenting because we are the ones responsible for providing that care." Review of RHS policy 1.1.14, entitled "Medical Screening and Evaluation", table 1.2c states that a "physical examination" must include, "Bimanual exam, including estimation of uterine size and	L1069		

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L1069	Continued From page 9 position and palpation of the adnexa." Review of Outpatient Gynecologic Surgery (Copyright 1997), by A. Jefferson Penfield, MD, FACOG, Associate Professor of the Department of Obstetrics and Gynecology at the State University of New York showed, " There is no situation in gynecology more fraught with possible confusion and error than a pelvic examination before an intended operative termination of pregnancy. Even those patients who are relaxed and easy to examine, not obese, and with clearly identifiable pelvic structures may lull the gynecologist into a false sense of security. In dealing with abortion under local anesthesia in women who are no more than 10 weeks from conception, it is essential for the operator first to determine the position of the uterus and to outline its dimensions as exactly as possible. With the corpus in an anterior position, estimation of size is not difficult unless the patient is tense or obese. Tension may be relieved by counseling, premedication, and gentleness, but obesity may force the examiner to rely principally on vaginal findings." Review of the Journal, Obstetrics and Gynecology, by Waldo Fielding, MD FACOG, Shiao-Yu Lee, MD FRCS(C), and Emanuel A. Friedman, MD, ScD, FACOG, from the chapter entitled, Continued Pregnancy After Failed First Trimester Abortion, shows, "Forty-six patients with unintentional continued pregnancy were detected among a series of 65,045 first trimester abortions. Patients at greatest risk are those with very early pregnancy and those with marked uterine anteversion or retroversion or with uterine anomaly...Thus, it appears that judgmental error inherent in the physician's estimation of gestational age constitutes a major component	L1069		

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underlying continuing pregnancy. Among 30 cases in which reasons could be found (or inferred), physician misjudgment accounted for more than half (53.3%). Anatomic factors constituted the only other important and frequently encountered explanation for failure to abort. Physician culpability here is also acknowledged; for purposes of emphasis, these cases in which technical skills are critical have been separated from those in which judgmental considerations are primary. They accounted for nearly all the remaining reasons among for whom logical reasons could be found. Included among them were 8 patients with uterine malposition (1 markedly anteverted and 7 markedly retroverted), 2 with congenital uterine anomaly (both bicornuate), 2 with leimyomata uteri, and 1 with a tortuous cervical canal. The difficulties of properly evacuating the gravid uterus under these circumstances are well recognized."

To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

2. Review of the medical record for Patient #2 showed she presented to RHS on [redacted], to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff B. The document is dated [redacted]. A transabdominal ultrasound was performed on the patient and gestational age was determined to be 9 weeks and 4 days. According to the record, Patient #2 demonstrated an understanding and "is prepared for the abortion".

Patient #2 presented to RHS for a surgical abortion on [redacted]. A physical examination is documented in the record as

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conducted by Staff B. Staff B documented the uterine orientation as "Mid" and the uterine size as "average". The procedure was performed at 11:00 a.m. by Staff B. The abortion was not performed under ultrasound. The patient's cervix was dilated to 27 and a 9mm cannula was used for the aspiration. The record notes that "procedure completed without difficulty" at the gestational age of "10 weeks and 2 days based on ultrasound". The document indicates that a gross examination of tissue was completed by the physician. "Some" fetal parts were seen by the physician and the report also indicates that the "tissue exam consistent with documented gestational age". Further, the document indicates the "procedure completed without complication".

The record includes a pathology requisition sent to Boyce and Bynum with the sample collected from Patient #2. The document identifies Staff B as the ordering physician and identifies the sample collection time and date as [redacted] at 9:25 a.m. The requisition orders are for "induced gross/micro - dispose" and identifies the sample as "10 w 2 days".

The record includes a pathology report, dated [redacted], read and electronically released by the pathology lab medical director. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 10-11 weeks gestational age. No evidence of villitis, chorioamnionitis, or atypical trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 8.0 x 8.0 x 2.0 cm in aggregate. Placenta and fetal parts are grossly identified. Representative sections are submitted in one block." An additional note, dated [redacted],

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L1069	Continued From page 12 [redacted] indicates, "Additional sections are submitted in three blocks". The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, placental membrane and decidua. 10 weeks 2 days". The record indicates Patient #2 contacted RHS on [redacted] at 1:05 p.m., and spoke to RHS staff. The record documents the patient contact as follows, "PT called stating "I don't believe the AB worked, my stomach is still getting bigger, I'm still throwing up! I just don't think he got it all." MSA confirmed callback number and gave her the number to the Medical Exchange." Patient #2 presented to RHS on [redacted], for post-abortion care. The record, dated [redacted], documents an ultrasound conducted by Staff B, with fetal gestational age to be 15 weeks and 1 day. Findings included are identified as, "cardiac motion, fetal pole, fetal movement, gestational sac with double ring sign, single". The clinical impression was documented as, "Continuing pregnancy post-abortion". Examination of the record showed the only informed consent document on file for Patient #2 was dated [redacted]. Patient #2 presented to RHS on [redacted], for an abortion. The record, dated [redacted], documents a physical examination of the patient conducted by Staff B. Staff B documented the uterine orientation as "Mid" and the uterine size as "average". The procedure was performed at 11:38 a.m. by Staff B. The abortion was performed under ultrasound. The patient's cervix was dilated to 39 and a 12mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "15 weeks 2 days Re-aspiration following surgical	L1069		

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abortion for on-going IUP". The document indicates that a gross examination of tissue was completed by the physician. "All" fetal parts were seen by the physician and the report also indicates that the "tissue exam consistent with documented gestational age". Further, the document indicates the "procedure completed without difficulty". The following additional visit comments were added to the record on [redacted] at 1:00 p.m., by Staff J, "[Staff B] at bedside, pt c/o severe increase in pain and dizziness, and states when she went to the bathroom had a moderate amount of bleeding/clot. [Staff B] reviewed pts vitals since admitted to clinic. Methergine 0.2 mg given IM. Small amount of bleeding noted on pad since pt returned to bed. Will continue to assess." Another note, documented at 1:15 p.m. by Staff J documents, "Pt clarified that pain she reports is "my tailbone" not uterine cramping, states she has no cramping at present. Pt states dizziness resolved. No additional bleeding noted on pads since last check. [Staff B] at bedside and observed bleeding and spoke with pt. States pt is ok for discharge. He recommended pt RTC for check up in 1-2 weeks, appt scheduled."

Staff B completed a complication report, dated [redacted], for the attempted surgical abortion on Patient #2 on [redacted]. The report indicates the reason for the complication was "Failed abortion/pregnancy undisturbed and Incomplete Abortion" The document is signed by Staff B.

The record includes another pathology requisition sent to Boyce and Bynum with the sample collected from Patient #2. The document identifies Staff B as the ordering physician and identifies the sample collection time and date as

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L1069	Continued From page 14 [redacted] at 8:10 a.m. The requisition orders are for "G/M/D-REASP" and identifies the sample as "15 weks 2 days". The record includes a pathology report, dated [redacted], read and electronically released by the pathology lab's assistant medical director. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 15-16 weeks gestational age. No evidence of villitis, chorioamnionitis, or atypical trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 8.0 x 8.0 x 5.0 cm in aggregate. Placenta and fetal parts are grossly identified. Representative sections are submitted in one block." The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, placental membrane and decidua. 15 weeks 2 days - Re-Aspiration". A review of records submitted to the DHSS Bureau of Vital Records revealed that a post-abortion care complication report was completed and filed for Patient #2 on [redacted], [redacted], for post-abortion care she received at the hospital on [redacted]. According to the report, Patient #2 presented for the treatment of "endometritis" and was given "IV Antibiotics". The record indicates the post-abortion care was provided at the hospital by RHS Staff O. An amended post-abortion care complication report was submitted to DHSS regarding Patient #2 on [redacted], for care provided to Patient #2 on [redacted], by Staff O. According to the amended report, Patient #2 presented to the hospital for the treatment of "endometritis" and "Hematometra" and as a result was given "IV Antibiotics, D&C".	L1069		

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L1069	Continued From page 15 Review of the hospital medical record for Patient #2 revealed that she presented to the hospital Emergency Room on [redacted]. The patient had become septic and had a fever of 104.2 degrees and a pulse of 154. The record indicates, "HPI: [redacted] yrs G6P6016, POD#2 s/p D&E at 15 weeks at RHS presents with fever, fatigue, abdominal soreness, and a headache. Found to have T of 40 in ED, w/ WBC of 17000, and tachycardic. Procedure was two days ago and per patient report uncomplicated. Since then has been having a normal amount of bleeding (<menses), but has feeling progressively more and more fatigued as well as a progressive headache and lower abdominal pain. She presents now because she is worried about her fever. Of note, she reports that in this same pregnancy she had a termination procedure at 11 weeks and then again 4 weeks later, [redacted], at 15 weeks "because they didn't get everything out and the baby still had a heart beat." Both procedures were performed at RHS here in St. Louis by [Staff B]. She was discharged home on Saturday with routine precautions/follow-up." The record indicates that Patient #2 was given IV antibiotics and discharged from the hospital on [redacted] In regard to RHS' failure to ensure prompt follow-up with Patient #2 after the patient called and complained of symptoms of a continuing pregnancy, Staff B declined an interview. On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked how soon the facility should respond to a patient who reports symptoms of a continuing pregnancy, he stated he would expect that the facility would accommodate the patient, "As soon as we can."	L1069		

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L1069	Continued From page 16 When asked if 15 days was too long a time period, he stated, "Patients have complicated lives ...I do not know why a patient would not come back for 15 days." In regard to the gross examination and identification of "some" fetal parts after the [redacted], failed abortion, Staff B has declined an interview. Review of RHS' Clinical Quality Assurance Committee Meeting" minutes, dated [redacted] revealed, "Reviewed #2 of [redacted] ReAsp visit followed by tx @ hospital D&C &IV Antibiotic, complication report completed at [redacted] visit. Cardiac Motion, [redacted], most likely a pregnancy missed of a twin; ..." The Department finds this explanation is insufficient to satisfy compliance with this requirement. Review of the Journal, Obstetrics and Gynecology, by Waldo Fielding, MD FACOG, Shiao-Yu Lee, MD FRCS(C), and Emanuel A. Friedman, MD, ScD, FACOG, from the chapter entitled, Continued Pregnancy After Failed First Trimester Abortion, shows, "Forty-six patients with unintentional continued pregnancy were detected among a series of 65,045 first trimester abortions. Patients at greatest risk are those with very early pregnancy and those with marked uterine anteversion or retroversion or with uterine anomaly..." Of the identified forty-six patients with unintentional continued pregnancy, none were determined to be twin pregnancies. In regard to Staff B's failure to conduct an informed consent with Patient #2 after she returned to the clinic on [redacted], after a failed surgical abortion on [redacted], Staff B has declined an interview.	L1069		

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L1069	Continued From page 17 On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that there be a new informed consent provided to a patient following a failed abortion and prior to a new surgical abortion procedure, he stated, "My understating is that the informed consent checklist is done once per pregnancy." He confirmed his understanding that if a second physician would treat a continuing pregnancy, they would have to perform a new informed consent checklist. He further confirmed that it was his expectation that a different procedural consent process be completed if the gestational age changes between the time of an initial failed abortion and the performance of a new abortion due to a continued pregnancy. He confirmed he expected the procedural consent to be present in the medical record. (Note: The change in the physiological and anatomical characteristics of the fetus as well as the change in the gestational age of the fetus would require the performance of a procedural consent, noting the changed risks and benefits to the procedure.) Review of RHS policy 1.1.21, entitled, "Early Complications and Problems", table 1.3.a, identifies the management of a "failed abortion" is to "Recounsel patient on pregnancy options". Review of the 2008 Reproductive Health Matters article, entitled, Complications after Second Trimester Surgical and Medication Abortion, by Daniel Grossman, Kelly Blanchard and Paul Blumenthal showed, "Second Trimester abortion is associated with higher rates of complications compared to first trimester terminations. Although the risk of complications is relatively	L1069		

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L1069	Continued From page 18 higher in the second trimester, the absolute risk is low when the termination is performed (in the case of surgical abortion) and managed (in the case of medical induction) by skilled practitioners." Review of the 2002 book entitled, Women's Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "The woman who seeks abortion is often promised a relatively painless and simple procedure to eliminate a pregnancy that she does not wish to carry to term. Failed abortion may involve her in a number of unanticipated outcomes. If she changes her mind about "medical" abortion and a child is born with anomalies, maternal grief and guilt may be anticipated and counseling may be necessary. If a second procedure is successful at a late stage of fetal development, where the woman knows that procedures are chosen to ensure that an anticipated live birth cannot occur, grief and guilt may likewise ensue." Further review of the 2002 book entitled, Women's Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "In the vast majority of cases of surgical abortion, a failed abortion - meaning that the fetus continues to survive or is not fully expelled - leads to a second surgery which itself raises the possibility of medical complications. Failed abortion is an extremely rare, but possible, result of induced surgical abortion. Nevertheless, in the United States alone, roughly 700 pregnancies a year continue following an initial abortion procedure, and that over the past 25 years about 17,500 women required either a second procedure, or a more serious surgery, or changed their mind and	L1069		

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L1069	Continued From page 19 continued the pregnancy to term." On April 3, 2019, Director of Surgical Services, Staff C was interviewed regarding communication with the contracted pathology lab. Staff C confirmed that none of the medical records contain a 24 hour notification from the pathologist of anything but completed abortions. She stated that all communication from the pathologist comes in the form of a pathology report. She stated that if something unusual were to be brought to her attention, she would contact the patient, if necessary. She denied that the pathologist had ever, to her knowledge, made contact with the facility due to a failed or incomplete abortion. (Note: An interview with Staff E indicated that Staff E denied ever having spoken to a Pathologist at Boyce and Bynum regarding her work at RHS.) The contract between RHS and Boyce and Bynum Pathology Laboratories was collected and reviewed on April 3, 2019. The contract, dated February 18, 2016, is signed by the former RHS CEO, with delivered services effective on February 5, 2016. In regard to the obligation of the pathologist referenced in Section 188.047.1 RSMo., the document notes, "Provider will comply with all state/federal laws and regulations governing the provision of pathology services and the disposition of fetal remains and tissue (subject to the will of the patient)". An addendum to the contract, dated October 20, 2017, and signed by the lab's Director of Compliance notes, "Boyce and Bynum Pathology Laboratories has reviewed Senate Bill 5, Truly Agreed and Finally Passed in the 99th General Assembly 2017 and will be implementing the necessary process	L1069		

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L1069	Continued From page 20 changes in order to comply with the provisions identified in 188.047 below ...Effective Monday October 23, 2017 Boyce and Bynum will begin reporting a microscopic exam on all specimens received. The fee for this service will be $30 per specimen submitted." [Note: On April 18, 2019, a referral was made to the Centers for Medicare and Medicaid Services (CMS) (MO0015502) in regard to CLIA #26D2160160, held by Boyce and Bynum in Columbia, MO. A survey of the facility was conducted on April 25, 2019. On May 7, 2019, CMS notified Boyce and Bynum and the Medical Director of the following deficient practices at the Condition level: CFR 493.1250 Analytic Systems; CFR 493.1290 Postanalytic Systems; CFR 493.1441 Laboratory Director; and CFR 493.1487 Testing Personnel. A letter to the facility and statement of deficiencies was sent to the facility for response. Boyce and Bynum was notified that they "must take steps to bring any unmet Conditions into compliance immediately". On June 6, 2019, Boyce and Bynum was notified that their submitted plan of correction was deemed acceptable by CMS.] Review of a "Committee Opinion" from The American College of Obstetricians and Gynecologists (ACOG), number 517, dated February 2012 and reaffirmed in 2016, shows, "Accurate communication of information about a patient from one member of the heath care team to another is a critical element of patient care and safety; it is also one of the least studied and taught elements of daily patient care. One of the leading causes of medical errors is a breakdown of communication. This breakdown may occur between clinicians at any level of the healthcare	L1069		

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system. Communication failures also have been found to be a leading cause of preventable error in studies of closed malpractice claims. In the era of collaborative care, effective clinician-to-clinician communication is important to facilitate continuity of care, eliminate preventable errors, and provide a safe patient environment."

Review of RHS policy 1.1.17, entitled, "Post Procedure Management" I.A, states, "Tissue evaluation is considered to be complete if all of the following occur: 2. In pregnancies of 10 to 13 weeks gestation, fetal parts are positively identified. 3. In pregnancies greater than or equal to 13 weeks gestation, all fetal parts must be accounted for, i.e., calvarium, spine, and four extremities." I.D.3., states, "Pathology examinations that yield unexpected results will be reported to an abortion provider clinician by phone within 24 hours."

Review of RHS policy 1.1.17 entitled, "Post Procedure Management" I.E, states, "Confirming Complete Abortion in Special Circumstances - in cases of known multiple gestation or known uterine anomalies less than or equal to 10 weeks gestation, must confirm complete abortion by: 1. Identification of 2 or more separate embryos or fetal parts or 2. Use of intra or post-operative ultrasound or 3. Follow-up visit involving ultrasound or hCG to confirm complete abortion."

In regard to the failure of RHS to contact Boyce and Bynum upon discovery of a failed abortion on [redacted], some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

3. Review of the medical record for Patient #3

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showed she presented to RHS on [redacted], to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. The document is dated [redacted]. A transabdominal ultrasound was performed on the patient and gestational age was determined to be 6 weeks and 0 days. According to the record, Patient #3 demonstrated an understanding and "is prepared for the abortion".

Patient #3 presented to RHS for a surgical abortion on [redacted]. A physical examination is documented in the record as conducted by physician fellow, Staff A. Staff A documented the uterine orientation as "Ant" and the uterine size as "6-8 weeks". The procedure was performed under moderate sedation at 2:48 p.m., by Staff A. The abortion was not performed under ultrasound. The patient's cervix was dilated to 19 and a 6mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "without complication" at the gestational age of "7Weeks 0 days based on LMP". The document indicates that a gross examination of tissue was completed by the physician with visible villi and membrane/sac. The note indicates the tissue was sent to the pathology lab.

An untitled document, referenced to patient #3, generated by Staff E, dated [redacted], at 8:40 a.m., states, "Supervising provider review for encounter on [redacted] 8:40 AM I was present for the procedure and agree with the treatment and follow up plan(s)."

The record includes a pathology requisition sent to Boyce and Bynum with the sample collected from Patient #3. The document identifies Staff E

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as the ordering physician and identifies the sample collection time and date as [redacted] at 8:40 a.m. The requisition orders are for "induced gross/micro - dispose" and identifies the sample as "6 weeks 6 days".

The record includes a pathology report, dated [redacted], read and electronically released by the Medical Director at Boyce and Bynum Pathology Laboratories. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 6-7 weeks gestational age. No evidence of villitis, chorioamnionitis, or atypical trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 5.0 x 5.0 x 0.5 cm in aggregate. Chorionic villi are identified; no embryonic tissue is recognizable. Representative sections are submitted in one block." The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, placental membrane and decidua. 6 weeks 6 days".

The record indicates Patient #3 contacted RHS on [redacted] at 1:35 p.m., and spoke to RHS staff. The record documents the patient contact as follows, "Received call from Call Center spoke w/pt who states she just left her Drs ofc & the Dr states she is 12 weeks pg. ReVac procedure scheduled for Tues [redacted]. Pre op instructions reviewed w/ pt who voiced understanding."

Patient #3 presented to RHS on [redacted], for an abortion. Staff E performed a physical examination on Patient #3 and determined the uterine orientation to be "Ant" and a uterine size of "12-13 weeks". The procedure was performed under moderate sedation at 10:42 a.m., by Staff

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L1069	Continued From page 24 E. The abortion was not performed under ultrasound. The patient's cervix was dilated to 31 and a 10mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "without complication" at the gestational age of "11 Weeks 6 days based on LMP". The document indicates that a gross examination of tissue was completed by the physician with "all" fetal parts seen and "consistent with documented gestational age". The note indicates the tissue was sent to the pathology lab. Examination of the record showed the only informed consent document on file for Patient #3 was dated [redacted]. Staff E completed a complication report, dated [redacted], for the surgical abortion attempted by physician fellow, Staff A on Patient #3 on [redacted]. The report indicates the reason for the complication was "Failed abortion/pregnancy undisturbed" The document is signed by Staff E. The record includes another pathology requisition sent to Boyce and Bynum with the sample collected from Patient#3. The document identifies Staff E as the ordering physician and identifies the sample collection time and date as [redacted], at 8:35 a.m. The requisition orders are for "G/M/D-REASP" and identifies the sample as "gestational age 10 weeks". The record includes another pathology report, dated [redacted], read and electronically released by the Medical Director at Boyce and Bynum Pathology Laboratories. The gross examination of the sample, as noted on the report, states, "Immature chorionic villi confirming products of conception consistent with 10 weeks gestational age. No evidence of villitis or atypical	L1069		

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trophoblastic proliferation. The specimen is received in formalin and consists of tan-pink soft tissue fragments measuring 8.0 x 8.0 x 4.0 cm in aggregate. Placenta and fetal parts are grossly identified. Representative sections are submitted in one block." The microscopic evaluation indicated, "The section demonstrates immature chorionic villi, decidualized endometrial mucosa, and trophoblastic proliferation consistent with implantation site. 10 weeks".

In regard to the gross examination and identification of "visible villi and membrane/sac" after the [redacted], failed abortion, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

On May 28, 2019, Staff E was interviewed. When asked if she is present in the room when a resident that she supervises performs an examination of the products of conception, she stated, "Not always." When asked if she was in the room during the procedure performed on Patient #3, she stated, "I don't know." She further stated, "A patient can have a continuing pregnancy and it still be true that products of conception were identified." She stated that the situation of having an ongoing pregnancy after having an aspiration abortion is "incredibly rare ...Less than 1% of the time do people have an ongoing pregnancy after aspiration abortion."

On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the supervising physician follow up with a resident who was found to have conducted or documented an examination of fetal tissue / products of conception inaccurately, he stated, "The residents are not providing the care,

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because they are not providing the care without that physician present." He stated that the residents never document care that is provided. He further stated, "We are documenting because we are the ones responsible for providing that care."

In regard to Staff E's failure to conduct an informed consent with Patient #3 after she returned to the clinic on [redacted], after a failed surgical abortion on [redacted], some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that there be a new informed consent provided to a patient following a failed abortion and prior to a new surgical abortion procedure, he stated, "My understating is that the informed consent checklist is done once per pregnancy." He confirmed his understanding that if a second physician would treat a continuing pregnancy, they would have to perform a new informed consent checklist. He further confirmed that it was his expectation that a different procedural consent process be completed if the gestational age changes between the time of an initial failed abortion and a re-aspiration due to a continued pregnancy. He confirmed he expected the procedural consent to be present in the medical record.

Review of RHS policy 1.1.21, entitled, "Early Complications and Problems", table 1.3.a, identifies the management of a "failed abortion" is to "Recounsel patient on pregnancy options".

Review of the 2002 book entitled, Women's

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L1069	Continued From page 27 Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "The woman who seeks abortion is often promised a relatively painless and simple procedure to eliminate a pregnancy that she does not wish to carry to term. Failed abortion may involve her in a number of unanticipated outcomes. If she changes her mind about "medical" abortion and a child is born with anomalies, maternal grief and guilt may be anticipated and counseling may be necessary. If a second procedure is successful at a late stage of fetal development, where the woman knows that procedures are chosen to ensure that an anticipated live birth cannot occur, grief and guilt may likewise ensue." Further review of the 2002 book entitled, Women's Heath After Abortion: The Medical and Psychological Evidence, by Elizabeth Ring-Cassidy and Ian Gentles, shows, "In the vast majority of cases of surgical abortion, a failed abortion - meaning that the fetus continues to survive or is not fully expelled - leads to a second surgery which itself raises the possibility of medical complications. Failed abortion is an extremely rare, but possible, result of induced surgical abortion. Nevertheless, in the United States alone, roughly 700 pregnancies a year continue following an initial abortion procedure, and that over the past 25 years about 17,500 women required either a second procedure, or a more serious surgery, or changed their mind and continued the pregnancy to term." On April 3, 2019, Director of Surgical Services, Staff C was interviewed regarding communication with the contracted pathology lab. Staff C confirmed that none of the medical records contain a report of anything but a completed	L1069		

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L1069	Continued From page 28 abortion. She stated that all communication from the pathologist comes in the form of a pathology report. She stated that if something unusual were to be brought to her attention, she would contact the patient, if necessary. She denied that the pathologist had ever, to her knowledge, made contact with the facility due to a failed or incomplete abortion. The contract between RHS and Boyce and Bynum Pathology Laboratories was collected and reviewed on April 3, 2019. The contract, dated February 18, 2016, is signed by the former RHS CEO, with delivered services effective on February 5, 2016. In regard to the obligation of the pathologist referenced in Section 188.047.1 RSMo., the document notes, "Provider will comply with all state/federal laws and regulations governing the provision of pathology services and the disposition of fetal remains and tissue (subject to the will of the patient)". An addendum to the contract, dated October 20, 2017, and signed by the lab's Director of Compliance notes, "Boyce and Bynum Pathology Laboratories has reviewed Senate Bill 5, Truly Agreed and Finally Passed in the 99th General Assembly 2017 and will be implementing the necessary process changes in order to comply with the provisions identified in 188.047 below ...Effective Monday October 23, 2017 Boyce and Bynum will begin reporting a microscopic exam on all specimens received. The fee for this service will be $30 per specimen submitted." [Note: On April 18, 2019, a referral was made to the Centers for Medicare and Medicaid Services (CMS) (MO0015502) in regard to CLIA #26D2160160, held by Boyce and Bynum in Columbia, MO. A survey of the facility was conducted on April 25, 2019.	L1069		

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L1069	Continued From page 29 On May 7, 2019, CMS notified Boyce and Bynum and the Medical Director of the following deficient practices at the Condition level: CFR 493.1250 Analytic Systems; CFR 493.1290 Postanalytic Systems; CFR 493.1441 Laboratory Director; and CFR 493.1487 Testing Personnel. A letter to the facility and statement of deficiencies was sent to the facility for response. Boyce and Bynum was notified that they "must take steps to bring any unmet Conditions into compliance immediately". On June 6, 2019, Boyce and Bynum was notified that their submitted plan of correction was deemed acceptable by CMS.] Review of a "Committee Opinion" from The American College of Obstetricians and Gynecologists (ACOG), number 517, dated February 2012 and reaffirmed in 2016, shows, "Accurate communication of information about a patient from one member of the heath care team to another is a critical element of patient care and safety; it is also one of the least studied and taught elements of daily patient care. One of the leading causes of medical errors is a breakdown of communication. This breakdown may occur between clinicians at any level of the healthcare system. Communication failures also have been found to be a leading cause of preventable error in studies of closed malpractice claims. In the era of collaborative care, effective clinician-to-clinician communication is important to facilitate continuity of care, eliminate preventable errors, and provide a safe patient environment." In regard to the failure of RHS to contact Boyce and Bynum upon discovery of a failed abortion on [redacted], some physicians who provided the care documented within the medical records	L1069		

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L1069	Continued From page 30 reviewed have refused to submit to interviews. On May 28, 2019, Staff E was interviewed. When asked to describe her process for when a pathology report comes back suggesting that no products of conception were seen, she stated, "The patient would be called and asked to come for further evaluation." She further stated, My guess is the only communication with the pathologist is the requisition with the POCs that we send. We don't typically have any communication with the pathologist." She denied any communication with the pathologist in regard to Patient #3. She denied ever communicating with a pathologist about any abortion she performed. On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that there be communication with the pathology lab upon a physician's discovery of a failed abortion, he stated, "If I become aware of a patient who has had a continuing pregnancy, despite an induced abortion being performed at Planned Parenthood, at RHS, we do discuss with pathology and review the pathology that was obtained at the time of the initial index abortion." When asked about the frequency of the occurrence of speaking with the pathologist regarding a failed abortion, he stated, "I honestly don't know. It's a regular occurrence in the practice of medicine." 4. Review of the medical record for Patient #4 showed she presented to RHS on [redacted], to provide informed consent for a surgical abortion. The record indicates the physician portion of the 72 hr. informed consent was completed by Staff H. A transabdominal	L1069		

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L1069	Continued From page 31 ultrasound was performed on the patient and gestational age was determined to be 6 weeks and 5 days. According to the record, Patient #4 demonstrated an understanding and "is prepared for the abortion". Patient #4 presented to RHS for a surgical abortion on [redacted]. A physical examination is documented in the record as conducted by physician resident, Staff G. Staff G documented the uterine orientation as "Ant" and the uterine size as "6-8 weeks". The record indicates the surgical time-out, to confirm correct patient identity, site and procedure "prior to the surgical procedure" was conducted by physician fellow, Staff A. However, the record identifies that the procedure was performed at 9:47 a.m., by Staff G. The abortion was not performed under ultrasound. The patient's cervix did not require dilation. A 7mm cannula was used for the aspiration. The physician notes that "procedure completed without difficulty" and "without complication" at the gestational age of "7 Weeks 1 day based on LMP". The document indicates that a gross examination of tissue was completed by the physician with visible villi and membrane/sac. According to the record, the physician saw no fetal parts. However, the physician noted that "Tissue exam consistent with documented gestational age." The note indicates the tissue was sent to the pathology lab. The record indicates Patient #4 contacted RHS on [redacted] at 8:49 a.m., and spoke to RHS staff. The record documents the patient contact as follows, "Pt is concerned with some bloating in her stomach, MSA confirmed call back number." An additional note in the record, documented by Staff J, on [redacted] at 11:55 a.m., states, "Returned pts call. Pt	L1069		

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L1069	Continued From page 32 concerned bc earlier today her stomach felt "bloated" and she is worried that she will need a re-vac bc "I needed one last time." Pt reports bloating has resolved, states she is eating well, drinking plenty of fluids, passing gas. Pt reports very little bleeding and no pain. Advised to do frequent fundal massage and call for heavy bleeding, pain unrelieved by massage and OTC meds, or fever. Advised OTC remedies for gas/bloating. Comfort/ reassurance offered. Emergency precautions reviewed. Qestions answered." On April 24, 2019, at approximately 10:55 a.m., an in-person interview was conducted with Staff J at the office of RHS' attorney in St. Louis, Missouri. Staff J confirmed that she was a Registered Nurse and had been employed by RHS for approximately 3 years and 8 months. She reports directly to a nurse supervisor for medical issues and Director of Surgical Services, Staff C for administrative issues at RHS. Her normal job duties include providing informed consent to patients on "informed consent days" and providing other medical care as assigned on "procedure days". Her assigned job duties also include making follow-up patient contact by telephone, should patients call in with medical concerns. She characterized her patient follow-up calls as: complaints of bleeding; pain; or anything the patient would consider a complication. During normal daytime operation of the facility, patient calls are received from the call center on the lower level of the facility and after hours, a third party call center transfers patient calls to her when she is "on call" and has the call phone. She stated she has access to the medical advice of a Nurse Practitioner or Physician when performing her duties related to patient follow-up calls. Staff J was provided the	L1069		

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L1069	Continued From page 33 "Patient Communication" record, dated [redacted], for Patient #4 for her review. Staff J confirmed she wrote the "Additional Visit Comments" dated [redacted] at 11:55 a.m. When asked about her direction to the patient to perform "frequent fundal massage", she stated the following: - Fundal massage is appropriate direction for a patient complaint of bleeding and cramping. - She originally thought that the direction was appropriate for any gestational age but was recently informed by a physician (could not identify) that a fundal massage may not make a difference for a gestational age of 8 weeks or under. - She demonstrated how she instructs patients to perform a fundal massage on themselves by placing her fist low on her abdomen and twisting her knuckles into her lower abdomen as if she was "kneading dough". - She has observed other nurses performing a fundal massage on patients in the RHS recovery room. She described the procedure the same and stated that the advantage of having a nurse perform the massage on the patient is that the nurse can massage from different angles. - She did not recall ever observing a physician performing a fundal massage. - At no time has she observed a physician or nurse place their hand in a patient's vagina to perform a fundal massage. 5. Review of the medical record for Patient #12 showed she presented to RHS for an abortion on [redacted]. The medical record includes an informed consent, signed by the patient and Staff H on [redacted]. However, Staff H included a note within the medical record to indicate, "Patient had 72 hour consent signed with this	L1069		

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writer at Washington University at 13:54 on [redacted]". The record showed that Staff H conducted a transabdominal ultrasound, "at WashU". However, no ultrasound results are within the RHS record. The physician notes, "I intend to perform a procedure using aspiration and/or removal of the fetus in multiple parts with multiple passes." A time-out is documented in the record as, "Time-out confirming correct patient identity, correct site and procedure to be done was performed prior to the surgical procedure by Staff N. The record notes that Patient #12 had a prior C-Section on [redacted] and "known placenta previa". A physician note within the record documents Patient 12's complication as follows: "[redacted] G4P2, h/o prior c/s x1 with known placenta previa admitted earlier this week with vaginal bleeding who presents today for day 1 of 2 day AB procedure. Pt has formal U/S at WashU which did not show e/o morbidity adherent placenta, complete previa. On placement of cervical dilators, by 3rd dilapan started having bright red bleeding. Continued placement of dilators did tamponade bleeding. Total EBL 200cc. Vag pack placed. Plan to transfer to BJH by EMS for in-hospital D&E. Pre-op Hgb 10.2 EMS called."

Review of the hospital medical record for Patient #12, dated [redacted], regarding the ultrasound conducted on the patient, the note indicates, "Anterior placenta previa - cannot exclude possible accreta on the basis of this scan, but there are no highly suspicious findings for such".

Further review of the hospital record for Patient #12 on [redacted], showed Staff H conducted a transvaginal and transabdominal ultrasound and dated the gestational age at 20 weeks and 4

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days with a "Suspected uterine abnormality, Previous cesarean delivery". The record notes Patient #12 was diagnosed with, "Placenta accreta in second trimester".

The record contains an "Emergency Transfer Form" for Patient #12. Patient #12 was transferred from RHS at 3:10 p.m., on [redacted], [redacted] to Barnes Jewish Hospital. Staff H requested the transfer.

Review of the hospital medical record for Patient #12, under "Assessment and Plan", dated [redacted], states, "Placenta previa in second trimester: she desires induced therapeutic abortion by standard D&E. She was counseled on pregnancy options and desires to proceed with termination of pregnancy. Consents were signed. I intend to perform a standard D&E."

Further review of the hospital medical record for Patient #12 revealed an informed consent was completed prior to the emergency surgery. The document states, in relevant part, "Options for the pregnancy were discussed with the patient, including continuation of pregnancy, medically induced abortion by labor induction, and surgically induced abortion by dilation and evacuation (D&E). Given the increased risk to maternal health or life endangerment from placenta previa, history of cesarean section, and possible placenta accreta, the patient desires not to continue the pregnancy. She is requesting an abortion by standard D&E."

Review of the medical record for Patient #12 revealed an Anesthesia note, prior to the emergency surgery on [redacted], stated, "PPH Bleeding requiring Uterine artery embolization. Patient lost around 2 to 2.5 litre of

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L1069	Continued From page 36 blood in OB operating room during termination of 23 week pregnancy. Received 1 unit of blood and 4 litre of crystalloids. 2 units of cross matched blood is on its way. Patient is already intubated and under general anesthesia." Review of the hospital record for Patient #12 on [redacted] documented the ICU History and Physical as follows, '[redacted]y.o. female presented to BJH today [redacted] from planned parenthood s/p laminaria placement with brisk vaginal bleeding (EBL 200ml) requiring vaginal packing (patient was 21 w 5d with pregnancy complicated by placenta previa. Due to this, she desired to have therapeutic termination of pregnancy). On arrival to BJH hemostasis had been achieved. She was taken to OR by Gynecology for a standard D&E. Her operative course was complicated by post-abortion hemorrhage with EBL of 1800ml. She was given 4L of crystalloid, 2 units of pRBCs, 1g TXA. Vaginal packing was inserted and a intrauterine foley balloon was placed. She was taken to IR for bilateral uterine artery embolization. The patient was sent to 7800 SICU for close monitoring and serial CBCs. The patient arrived hemodynamically stable and unsupported." Review of the medical record for Patient #12, under "Description of Procedure", states, "The lower uterine segment was atonic and the area of her prior cesarean delivery on the anterior and posterior walls of the lower uterine segment was noted to be thin but intact. 0.2mg IM Methergine, 250mcg Hemabate, 800mcg Misoprostol, and 30U IV Pitocin were administered sequentially with minimal improvement in uterine tone. The suction curette was introduced again with further evacuation of clot. The endometrium was noted to have gritty texture in all 4 quadrants."	L1069		

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L1069	Continued From page 37 The record notes that Patient #12 was discharged from the hospital on [redacted]. Review of RHS policy 1.1.12, entitled, "Contraindications and Special Conditions - Surgical Abortion", in the treatment table labeled 1.2b, the condition of "Insertion of osmotic dilators, if required" states, "Must evaluate and determine the appropriate management or referral." The same table lists the requirement for treating the uterus condition of "scarred" as, "All patients greater than or equal to 14 weeks gestation with scarred uterus and placenta previa and/or a placenta overlying the incision site must be evaluated for placenta accreta/increta/percreta. Studies sufficient for diagnosing an invasive placenta in a patient less than 14 weeks gestation can be performed at the affiliate with the appropriate equipment, training and skill to do so. Patients with a reassuring evaluation may have an outpatient D&E by surgeon experienced in these types of procedures. Experience is determined by the medical director or program director." Review of a Practice Bulletin from The American College of Obstetricians and Gynecologists (ACOG), entitled, Second-Trimester Abortion number 135, dated June 2013 and reaffirmed in 2015, shows, "Women with prior cesarean deliveries are at an increased risk of placenta accreta and warrant special attention, particularly if ultrasonography indicates a low-lying placenta or placenta previa. When there is a suspicion of abnormal placentation, D&E is the preferred abortion method, and preparations should be made for possible hemorrhage by ensuring the procedure is performed at an appropriate facility with accessibility to blood products, interventional	L1069		

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radiology, and the capability to perform a hysterectomy if necessary. Because the positive predictive value of ultrasonography to diagnose placenta accreta may be as low as 65%, preoperative uterine artery embolization is not generally recommended. Although the diagnostic accuracy of magnetic resonance imaging is similar to ultrasonography for placenta accreta, magnetic resonance imaging may be useful to confirm accreta and identify patients who should be referred to a tertiary care center that has interventional radiology and surgical services immediately available."

Review of an Article, dated August 7, 2018, in the Society for Maternal-Fetal Medicine (SMFM), entitled, Clinical Diagnosis of Placenta Accreta and Clinicopathological Outcomes, by: Rosenbloom; Hirshberg; Stout; Cahill; Macones and Tuuli, states, "There were 50 cesarean hysterectomies performed for suspected abnormal placentation from 2000 to 2016. Of these 34 (68%) had a diagnosis of accreta preoperatively and 16 (32%) were diagnosed intraoperatively at the time of cesarean delivery."

To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.

On May 28, 2019, Staff I, RHS Medical Director was interviewed. He denied RHS has a blood bank. He denied that RHS has interventional radiology capabilities. He denied that RHS has the capability to perform a hysterectomy. When asked if RHS was an appropriate setting for a planned abortion for a patient at 21 weeks and 5 days gestational age with a previous history of a C-section and a diagnosis of placenta previa, he stated, "We have very careful evidenced based

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L1069	Continued From page 39 guidelines about how we practice medicine and it is without a doubt safe to do an abortion in the second trimester even with a patient who has had a previous C-Section when that patient has been properly assessed for the clinical appropriateness for the location of care." When asked if a proper assessment include an MRI for the described patient's medical condition, he stated, "It depends on the circumstances. Generally, no."	L1069		
L1076	19 CSR 30-30.060(1)(A)(8) The governing body, ensure abortion facility The governing body, through the administrator, shall ensure that the abortion facility abides by all applicable state and federal laws and regulations. This shall include, but not be limited to, compliance with Chapter 188, RSMo. This regulation is not met as evidenced by: Based on facility record review and state law, the facility failed to ensure: - the Department of Health and Senior Services was able to complete an investigation, as required by Chapter 197.230 RSMo to include failing to induce, encourage, compel, or motivate the physicians who provide patient care at RHS to submit to interviews and failing to ensure the collection of relevant medical records; - the physician performing the informed consent was the same physician performing the abortion, for 8 patients (Patients: #1 #3; #4; #6; #8: #9; #10; and #11), as required by Chapter 188.027.6 RSMo; - a complication report was completed and filed for a failed abortion for 1 patient (Patient #1), as required by Chapter 188.052.2 RSMo.	L1076		

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L1076	Continued From page 40 Findings included: 1. Chapter 197.230.1 RSMo. states, "The department of health and senior services shall make, or cause to be made, such inspections and investigations as it deems necessary. The department may delegate its powers and duties to investigate and inspect ambulatory surgical centers or abortion facilities to an official of a political subdivision having a population of at least four hundred fifty thousand if such political subdivision is deemed qualified by the department to inspect and investigate ambulatory surgical centers. The official so designated shall submit a written report of his or her findings to the department and the department may accept the recommendations of such official if it determines that the facility inspected meets minimum standards established pursuant to sections 197.200 to 197.240." DHSS inspectors conducted an unannounced, onsite complaint investigation at RHS on April 2 and April 3, 2019. At that time, a request was made to conduct an in-person interview with Staff A (Physician-fellow). RHS Director of Surgical Services, Staff C denied the request and told inspectors she would work to reschedule the interview for a more convenient time. A request was also made for telephonic contact information for Staff B (Out of state physician). Staff C also denied the request and stated that if telephonic contact was required, she would allow inspectors to be present when Staff B was contacted by the RHS Interim CEO, Staff D. On April 3, 2019, an attempt was made to conduct an in-person interview with Staff A at her alternate work location. Staff A was "in-clinic" and	L1076		

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unavailable for interview at that time. Contact information for the DHSS was left at Staff A's work place and telephonic contact was requested.

On April 3, 2019, at approximately 3:00 p.m., Staff C was interviewed via telephone and stated that all RHS physicians were unavailable for interview during the week of April 1, 2019, due to their primary work schedules at the hospital. She agreed to coordinate dates and times the physicians would be available during the week of April 8, 2019, and make contact regarding their availability for interview.

On April 11, 2019, an email was sent to the RHS Director of Surgical Services, Staff C and the RHS Interim CEO, Staff D, requesting they make the following practitioners available for interview: Staff A (Physician- fellow); Staff B (Physician-Out of State); Staff E (Physician); Staff F (Physician-resident); Staff G (Physician - resident); Staff H (Physician); Staff I (Physician- Medical Director); and Staff J (Nurse). They were asked to respond by the close of business on April 16, 2019.

On April 16, 2019, DHSS became aware through contact with RHS' attorney that each of the requested physicians were represented by outside counsel. Multiple documented unsuccessful attempts were made to arrange for in-person interviews with facility physicians. At the date of this writing, Staff A, Staff B, Staff F, Staff G and Staff H have declined an invitation to submit to interviews. These physicians provided the care documented within the medical records reviewed.

An excerpt from a letter received from RHS' attorney, dated May 3, 2019, showed, "Further,

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L1076	Continued From page 42 the Department cited no authority allowing its employees to "collect" protected patient records and remove them from RHS' facility (rather than just "inspecting" them onsite). As you are aware, patient medical records are of the upmost sensitivity and that is even more the case when we are talking about women who exercised their constitutional right to privacy. Therefore, we also request that prior to the Department removing any additional files from RHS, you provide your authority permitting Department employees to remove protected patient records from RHS' facility". On May 8, 2019, an announced, onsite visit to RHS was conducted at approximately 10:00 a.m., in order to collect and review additional relevant facility records. A written request for copies of the following records was given to facility staff: the patient roster for [redacted] medical record and informed consent document for each patient seen on [redacted] the RHS policy and procedure manual; informed consent document for the procedure performed on patient #2 on [redacted] and the informed consent document for the procedure performed on patient #3 on [redacted] RHS Clinical Manager, Staff K and Clinical Quality Manager, Staff L refused to make copies of the requested records, citing patient privacy concerns and the advice of RHS' attorney. When asked about the privacy concerns regarding providing a copy of the policy and procedure manual, they again refused to provide a copy and referred the request to RHS' attorney. They agreed to allow a visual review of the electronic records requested. On May 11, 2019, RHS provided electronic copies of the requested medical records and policy manual to the Department.	L1076		

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L1076	Continued From page 43 Review of DHSS electronic records showed that between April 4, 2001 and May 29, 2018, there were 19 complaint investigations completed and 16 licensure / revisits completed at RHS. Interviews with facility staff, including physicians and the collection of facility medical records and policies are documented regularly and routinely throughout the inspection record. Inspectors have not previously been denied requested records or interviews with staff, as deemed necessary. On May 24, 2019, at 5:30 p.m., the attorney representing Staff E and Staff I agreed to permit their clients to submit to interviews on May 28, 2019. 2. Chapter 188.027.6 states, "The physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of: (1) The immediate and long-term medical risks to the woman associated with the proposed abortion method including, but not limited to, infection, hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion; and (2) The immediate and long-term medical risks to the woman, in light of the anesthesia and medication that is to be administered, the unborn child's gestational age, and the woman's medical history and medical conditions. Medical records were obtained and reviewed for the following patients: Patient #1 was previously cited on the SOD dated, March 13, 2019.	L1076		

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L1076	Continued From page 44 Patient #3 signed an informed consent on [redacted] The physician who was to perform the abortion, Staff E, also signed the document. Patient # 3 initialed the document to confirm, "I have been provided the name of the physician who is to perform or induce the abortion and a contact number where the physician may later be reached if I have questions". Patient #3 further confirmed, "I have had the opportunity to ask any questions of the physician who is to perform or induce the abortion concerning the abortion." Additionally, Patient #3 confirmed, "I certify that the physician who is to perform or induce the abortion informed me orally and in person, at least 72 hours prior to the procedure, of ..." the requirements of Chapter 188.027.6. Patient # 3 presented to the facility for a surgical abortion on [redacted] The procedure was performed by Staff A. The medical record for Patient #4 indicated the informed consent was completed on [redacted] The informed consent document was not present in the medical record. However, the record documented the physician who was to perform the abortion, Staff H, provided the informed consent for Patient #4. Patient # 4 presented to the facility for a surgical abortion on [redacted] The procedure was performed by a physician resident, Staff G. The following patient records were requested and initially refused. However, DHSS inspectors were able to view the records on-site and obtained the redacted records on May 11, 2019: Patient #6 signed an informed consent for an abortion with Staff E on [redacted] Physician (resident), Staff F performed the	L1076		

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L1076	Continued From page 45 procedure on [redacted] Patient #8 signed an informed consent for an abortion with Staff E on [redacted] Physician (resident), Staff F performed the procedure on [redacted] Patient #9 signed an informed consent for an abortion with Staff E on [redacted] Physician (resident), Staff F performed the procedure on [redacted] Patient #10 signed an informed consent for an abortion with Staff E on [redacted] Physician (fellow), Staff A performed the procedure on [redacted] Patient #11 signed an informed consent for an abortion with Staff E on [redacted] Physician (fellow), Staff A performed the procedure on [redacted] Review of RHS policy 1.2 , section II.C.5. shows, "The providing physician must inform the woman orally and in person: a. The immediate and long term medical risks to the woman associated with the proposed abortion method including, but not limited to, infection, hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term and possible adverse psychological effects. b. Immediate and long term risks of in light of anesthesia and medication that is to be administered, the gestational age and the woman's medical history and medical conditions." To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.	L1076		

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L1076	Continued From page 46 On May 28, 2019, Staff E was interviewed. When asked when she conducts informed consent with a patient, if she has knowledge that she will not be performing the abortion, she stated, "I intend to perform every abortion for every consent that I sign ...I consider all the abortions performed when I am supervising them to be abortions that I performed." Staff E admitted that she was not always physically present in the procedure room during an abortion procedure, performed by a resident or fellow she supervises. When asked the meaning of "I was present for the procedure and agree with the plan", as noted in the medical records reviewed, she stated, "It means I was available in the surgical suite at the time the procedure was performed or may have been in the room ..." She further confirmed that she provided informed consent to multiple patients, knowing that she may not later perform the actual abortion. When asked if the physician who performed the abortion was present in the room for the informed consent, she stated, "No. I can't be sure, but no ... They are rarely, if ever in the room with us during consent". She further explained how providing informed consent to a patient, while knowing that she may not perform the abortion is consistent with the requirement, by stating, "As the Supervising Physician, I am ultimately responsible for the care of the patient and that can mean I have any varying degrees of hands-on experience in the actual room ...In general, given that I am the supervising and ultimately responsible attending physician, that is how I would say it's consistent." On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the physician performing the informed consent would be the same physician who performs the abortion procedure, he stated,	L1076		

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L1076	Continued From page 47 "The physicians who perform the consent are responsible for the care that's provided on the procedure day and they are performing the procedures that are provided under their name and under their supervision." When asked if it was his expectation that the supervising physician be physically present in the room during an abortion procedure performed by a resident or fellow, he stated, "It depends on the circumstances. The attending physician is responsible for the care that is provided by the team of physicians that day. They are present in the building. They are present in the room at times. But there is a graduated level of responsibility and privileging for our fellows that allows them to provide some care without, um, present in the room is not always required." Review of the medical record for Patient #12 revealed an institutional knowledge of the requirement. In relevant part, the informed consent portion of the record indicated, "She is aware that should she need to reschedule her abortion procedure to be provided by a different physician that she will need to meet with the physician performing the abortion in person at least 72 hours prior to the procedure ..." (Please note: On May 28, 2019, at approximately 11:30 a.m., RHS submitted a Plan of Correction for this identified deficiency. After review, the submitted plan was found to be acceptable.) 3. Medical record review for Patient #1 showed she presented to RHS on [redacted] to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. Patient #1 presented to RHS for a surgical abortion on [redacted] Staff A	L1076		

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L1076	Continued From page 48	L1076		

performed the procedure at 11:35 a.m. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated [redacted] at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated [redacted] at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated [redacted] at 12:00p.m. No complication report for the failed surgical abortion is within the medical record.

On April 3, 2019, during an interview with RHS' Director of Surgical Services, Staff C, when asked about the existence of a complication report for the failed surgical abortion attempt on Patient #1, she stated that the procedure was not considered a complication.

On May 28, 2019, Staff E was interviewed. When asked if she considered the abandonment of a surgical abortion a complication, she stated, "I consider that we weren't able to complete the abortion at that time." When asked if she considered what happened to Patient #1 a failed

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abortion, she stated, "No, because then we had a plan for medication abortion. We still had a plan to complete the procedure for her." When asked if she knew if a complication report was filed regarding the surgical abortion, she stated, "I don't know, but I don't consider that to be a complication, so I wouldn't necessarily expect one to be". The Department finds this explanation is inconsistent with RHS' own policy manual and insufficient to satisfy compliance with this requirement.

On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that a complication report be completed for an abandoned surgical abortion, he clarified, "So the decision to change the route of the termination from surgical to medication abortion? No. My understanding of when a post abortion complication report is required is after the abortion is completed." He confirmed knowledge of the statutory requirement to complete and file an abortion complication report for every complication. He further stated, "We follow that requirement."

Review of RHS policy 1.1.21, entitled, "Early Complications and Problems", table 1.3.a, identifies "cervical stenosis / inability to dilate" and "false passage" as complications.

19 CSR 30-30.050(1)(D) defines a complication as including, "but is not limited to, incomplete abortion, hemorrhage, endometritis, parametritis, pyrexia, pelvic abscess, uterine perforation, failed abortion, cervical lacerations, retained products, or diagnosable psychiatric condition;"

To date, some physicians who provided the care documented within the medical records reviewed

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L1076	Continued From page 50 have refused to submit to interviews.	L1076		
L1119	19 CSR 30-30.060(3)(B) The facility shall maintain a medical record The facility shall maintain a medical record according to professional standards for each patient. This regulation is not met as evidenced by: Based on facility record review and interview, the facility failed to ensure: - the medical records were maintained in a manner that accurately documents the time and date a record was created or amended and any specific amendments made to the record; - the medical record accurately identified the identity of the physician inducing a medication abortion for 1 record; - the medical record accurately documents a record of supervision for residents and fellows performing abortions at the facility for 2 records. Findings included: 1. Medical records reviewed during the course of this investigation showed significant documented differences between the "Encounter date" and the "Current date". The following records were collected and reviewed: - Patient #1 presented to RHS for a surgical abortion on [redacted] The medical record recording the visit notates an "encounter date" of [redacted] and a "current date" of [redacted] - Patient #1 presented to RHS on [redacted], for post-abortion care. The medical record	L1119		

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L1119	Continued From page 51 recording the visit notates an "encounter date" of [redacted] and a "current date" of [redacted] - A medical record, referenced to patient #3, generated by Staff E, dated [redacted] at 8:40 a.m.(approximately 6 hours prior to the start of the procedure), states, "Supervising provider review for encounter on [redacted] 8:40 AM I was present for the procedure and agree with the treatment and follow up plan(s)." - Patient #3 presented to RHS on [redacted] for post-abortion care. The medical record recording the visit notates an "encounter date" of [redacted] and a "current date" of [redacted] - Patient #4 presented to RHS for a surgical abortion on [redacted] The medical record recording the visit notates an "encounter date" of [redacted] and a "current date" of [redacted] - A medical record, referenced to patient #4, generated by Staff H, dated [redacted] at 8:40 a.m.(approximately 1 hour prior to the start of the procedure), states, "Supervising provider review for encounter on [redacted] 8:40 AM I was present for the procedure and agree with the treatment and follow up plan(s)." On April 3, 2019, Staff C stated that the "encounter date" represents the date the patient was seen. She explained that each time a patient "checks out" after their appointment, the electronic record is locked and no one can get into the medical record without unlocking the record. The "current date" represents when the record was last unlocked and relocked. She stated that the "current date" may be different due to a number of reasons: The front desk clerk failed to check a patient out from their original appointment or a correction was made to the visit	L1119		

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L1119	Continued From page 52	L1119		

summary (spelling, grammar), which would require "running" a new visit summary. She denied that a medical record can be amended without an addendum being added to the record and no physicians have access to unlock the records. She identified herself, two staff nurses and a front desk clerk who have access to "unlock" the records. She is able to determine who was in the record but not for what purpose.

In regard to the record for Patient #1 on [redacted] she stated that the "system does not show me that anyone was in there. The front desk clerk must have just checked her out on [redacted]

In regard to the record for Patient #1 on [redacted] she stated that the front desk clerk was in the record on [redacted] She could not determine the clerk's purpose for being in the record.

In regard to the records for Patients #3 and Patient #4, she stated that the system shows that she was in the records and could not recall the purpose of unlocking the records.

On May 28, 2019, Staff E was interviewed. When asked to explain the difference between the "encounter date" and the "current date" within the medical record, she stated, "I have no idea. That's an informational technology thing. It's how documents are generated. I don't know the answer to that." Staff E denied changing the record. She denied that she had access to "unlock" a record to change the record.

For records scanned into the system and not created within the electronic medical record, such as complication reports and informed consent

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L1119	Continued From page 53 documentation, Staff C stated that there is no way to determine at what date and time the record was scanned into the medical record. 2. Review of the medical record for Patient #1 showed she presented to RHS for a surgical abortion on [redacted] A physical and pelvic examination is documented in the record as conducted by physician resident, Staff F. Staff F documented the uterine orientation as "Ant" and the uterine size as "less than 6 weeks". The procedure was performed at 11:35 a.m. by physician fellow, Staff A. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated [redacted] at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated [redacted] at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The recorded entry was made by Staff J. The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated [redacted] at 12:00p.m. The section of the record entitled, "Medications Prescribed During this Visit" indicate that a 200 mg Mifeprex was "po administered to pt. in clinic" by [RHS Medical Director, Staff I].	L1119		

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L1119	Continued From page 54 On May 28, 2019, Staff E was interviewed. When asked about the medication abortion of Patient #1, she stated, "I handed her the pill and watched her take it." When asked why the record reflects that Staff I administered the pill to induce the abortion, she stated, "So, [Staff I] as the Medical Director, often times the scheduling, it's a scheduling issue. Under which, it has nothing to do with him actually physically giving the medication ....As the Medical Director, he would be the one for whom the medication is ordered from for the clinic, so he would be the dispensing to me who was the person who administered the medication." On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the medical record accurately reflect the role of each practitioner and are timed and dated accurately, he stated, "So the medical record should be accurate, period. It should be complete. It should reflect the medical care that is provided. There are elements of the medical record that require time stamps, based on clinical utility that should be included." 3. Review of the medical record for Patient #1 showed she presented to RHS for a surgical abortion on [redacted] The abortion was performed at 11:35 a.m. by physician fellow, Staff A. A complication occurred during the performance of the surgical abortion and the procedure was abandoned. A medication abortion was initiated. An untitled document, referenced to patient #1, generated by Staff E, dated [redacted] at 9:20 a.m., states in part, "Supervising provider review for encounter on [redacted] 9:20 AM I	L1119		

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L1119	Continued From page 55	L1119		

was present for the procedure and agree with the treatment and follow up plan(s)." Further, the document noted, "pt. with an very acutely retroflexed uterus and the pregnancy at the fundus. Although the canal and path was able to be appreciated with eth17F Pratt dilator, the angle and traction on the cervix was quite uncomfortable for the patient. The position of the uterus made TA u/S ineffective. TV U/S was able to confirm the path, but given the unique position of the uterus and pts discomfort, coupled with early gestational age, we opted to stop the Sab and proceed with MAB. Discussed and explained with patient. Questions answered."

On [redacted] Staff E performed a successful surgical abortion on Patient #1.

On May 8, 2019, medical records were reviewed for all procedures completed on [redacted] at RHS. Staff K and Staff L initially refused to provide copies of the records. The requested records were provided on May 11, 2019. Review of the records showed:

- Patient #13 signed an informed consent for an abortion with Staff E on [redacted] Staff E performed the procedure at 1:14 p.m., on [redacted] The record does not denote a procedure end time.

- Patient #8 signed an informed consent for an abortion with Staff E on [redacted] Physician resident, Staff F performed the procedure at 1:15 p.m., on [redacted] The procedure ended at 1:19 p.m. The records contains a supervisory note. The note pertaining to the supervision of Patient#8's abortion is dated [redacted] at 9:05 a.m. The note indicates Physician E was "present for the

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L1119	Continued From page 56 procedure and agree the treatment and follow up plan(s)." On May 28, 2019, Staff E was interviewed. When asked to explain why the supervisory record for Patient #1 was documented as completed over an hour prior to the procedure taking place, she stated, "The document is generated based on the patient's appointment time. So, if we looked, her appointment time would have been 9:20 a.m." On May 28, 2019, Staff I, RHS Medical Director was interviewed. When asked if it was his expectation that the medical record accurately reflect the time the supervising physician was present in the room during the abortion procedure, he stated, "I don't know that I have an expectation regarding the time." To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews.	L1119		
L1129	19 CSR 30-30.060(3)(H) The facility shall ensure, complication reprt The facility shall ensure that an individual complication report for any complication care provided via the facility is submitted to the department within forty-five (45) days of the care as required by section 188.052, RSMo, and 19 CSR 10-15.020. This regulation is not met as evidenced by: Based on Department and facility record review and interview, the facility failed to ensure: - a complication report for 1 failed medication abortion was submitted to the department, as	L1129		

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L1129	Continued From page 57	L1129		

required.

Findings included:

1. Medical record review for Patient #1 showed she presented to RHS on [redacted] to provide informed consent for a surgical abortion. The informed consent document is present in the file and is signed by the patient and Staff E. Patient #1 presented to RHS for a surgical abortion on [redacted] Staff A performed the procedure at 11:35 a.m. The abortion was not performed under ultrasound. The patient's cervix was dilated to 21 and a 7mm cannula was used for the aspiration. The physician notes that "procedure completed with difficulty MVA activated with no tissue returned." Additional visit comments, entered into the record and dated [redacted] at 12:00 p.m., state, "Uterus anteverted but retroflexed. Dilated to 21Fr and 7mm cannula passed. MVA deployed with no tissue or blood returned. Ultrasound brought to room. Attempted again to pass dilator with visualization with both transvaginal and transabdominal ultrasound views utilized. Unsuccessful in attempt to visualize dilator on US so procedure abandoned. Will plan for medication abortion." A note in the record dated [redacted] at 12:45 p.m., states, "Medication AB teaching completed and HCG drawn. Follow up apt scheduled." The record includes a "patient agreement" form for the administration of Mifeprex. The agreement is signed by the patient and Staff E and is dated [redacted] at 12:00p.m.

The record indicates Patient #1 contacted RHS on [redacted] at 12:05 p.m., and spoke to a nurse, Staff J. The record documents the patient contact as follows, "Spoke with pt who

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reports only mild cramping and scant bleeding since taking misoprostol at 530pm last evening. Encouraged pt to wait thru tonight to give misoprostol the full 24 hrs to work and if she still thinks she has not passed the pregnancy tomorrow morning to return to clinic. Pt verbalized an understanding of plan and states she will comply. [Staff E] aware and agrees with plan."

Patient #1 presented to RHS on [redacted] for post-abortion care. The record, dated [redacted] documents an ultrasound was conducted. Findings included are identified as, "yolk sac, cardiac motion, fetal pole, gestational sac with double ring sign, single". The visit comment in the record states, "Pt returned to clinic with continuing pregnancy confirmed on sono. Pt desires to have evacuation today if possible. Pt reports only spotting and mild cramping after taking misoprostol at home at 530pm on [redacted] (more than 24 hrs ago). Discussed with [Staff E] who ordered pt receive misoprostol and IV sedation and will attempt in clinic procedure. Discussed with pt who is in agreement. The visit comment is recorded by Staff J at 11:00 a.m. on [redacted] The procedure was performed at 12:56 p.m. by Staff E. The abortion was performed under ultrasound. The patient's cervix was dilated to 25 and a 9mm cannula was used for the aspiration. The physician notes that the procedure was completed without difficulty. An additional comment in the record, dated [redacted] 1:05 p.m., from an unknown author, states, "S/p failed Sab 2/2 dicomfotr and uterune position. Attempted MAB without success. USe of IVS and U/S guidance was able to evacuate without diffciluty. Extremely RV and Retroflexed".

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1129	Continued From page 59 The record contains a completed complication report, dated [redacted] for the MAB attempted on Patient #1 on [redacted] The report indicates the reason for the complication was "Failed abortion/pregnancy undisturbed" The document is signed by Staff E. On April 3, 2019, a review of records received by the DHSS Bureau of Vital Records from RHS was conducted. Review of the records showed no complication report submitted for Patient #1. On April 3, 2019, at approximately 11:00 a.m., the Clinical Quality Manager, Staff L was interviewed regarding the process for submitting a complication report to the State of Missouri. Staff L stated that the process is manual, in that each form is paper and not electronic. She further noted that each complication report is bundled, by month and sent via certified mail to the BVR within the allowable timeframe. Staff L provided a copy of the bundled record that she provided to BVR representing complications that occurred in [redacted] Contained within the bundle is the complication report for Patient #1. Staff L signed the cover letter sent to the BVR and the letter is dated [redacted] The certified mail receipt is stamped as received at BVR on [redacted]	L1129		
L1169	19 CSR 30-30.060(8)(C) The QAPI program shall show evidence of actio The QAPI program shall show evidence of action the facility took regarding problems identified and shall identify opportunities for improvement. This regulation is not met as evidenced by:	L1169		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/28/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L1169	Continued From page 60 Based on facility record review and review of the standards of medical care, the facility failed to ensure: - the appropriateness of the care provided at the facility was reviewed regarding the occurrence of 3 failed abortions documented within the medical records from [redacted] through [redacted] - that action was taken regarding problems identified in the medical care provided at the facility, regarding the failed abortions. Findings included: 1. See referenced evidence of facility deficient practices at: 19CSR30-30.060(1)(A)(1); 19CSR30-30.060(1)(A)(8); 19CSR30-30.060(3)(B); and 19CSR30-30.060(3)(H). To date, some physicians who provided the care documented within the medical records reviewed have refused to submit to interviews. Review of RHS' Clinical Quality Assurance Committee Meeting" minutes, dated [redacted] revealed, "Reviewed #2 of [redacted] ReAsp visit followed by tx @ hospital D&C &IV Antibiotic, complication report completed at [redacted] visit. Cardiac Motion, [redacted], most likely a pregnancy missed of a twin; ..." The Department finds this explanation is insufficient to satisfy compliance with this requirement. Between [redacted] and [redacted] Staff A performed at least 2 failed abortions, as documented within the medical records reviewed. As of the date of this writing, Staff A has refused to submit to an interview with DHSS Inspectors. On May 28, 2019, Staff E was interviewed. When	L1169		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 05/28/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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L1169	Continued From page 61 asked about the frequency of failed abortions, she stated, "A failed abortion is less than 1% of all the abortions that we take care of and I would say that's consistent with what I have seen." When asked about the frequency of complications at RHS, she stated, "You have to have a denominator. This is still incredibly rare and consistent with the expected amount of failed abortions, 1% or less."	L1169		

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Reproductive Health Services	Survey Exit Date	05/28/19
Facility Address/ City/Zip	4251 Forest Park Ave. St. Louis, MO 63108	Statement of Deficiencies (SOD): L-tags	L-1069; L-1076; L-1119; L-1129; L-1169

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages.

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

Americans United for Life

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L-1069	As an initial matter, the deficiencies under this tag are based on the Department's unsupported and inexpert opinion of what constitutes "acceptable care in a safe environment and in accordance with all legal requirements and standards of care." 19 CSR 30-30.060(1)(A)(1). The Department does not purport to be enforcing any specific legal or regulatory requirement; rather, it has determined that its judgment of "acceptable care" should supplant the considered, evidence-based, and tested judgment of experienced, highly trained clinicians who are experts and specialists in the provision of abortion care and who are providing that care pursuant to nationally recognized standards and guidelines. This is not an appropriate exercise of the Department's regulatory function. And indeed, the Department does not even attempt to offer an expert opinion, as would be required to establish the standard of care in a malpractice or disciplinary context. *See, e.g.*, *State Bd. of Registration for Healing Arts v. McDonagh*, 123 S.W.3d 146 (Mo. 2003). Nor does the Department support its position with citations to appropriate medical literature, instead relying in large part on anti-	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
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	abortion propaganda, literature from the '70s, and misrepresentations of fact. As set forth more fully below, neither the literature nor the guidance of professional organizations with specialized expertise support the Department's assertions as to standard of care. (1) The Department's contention that RHS failed to ensure "the pelvic examination was completed at the time of the health assessment and in a manner to accurately document the size and orientation of Patient #1's uterus prior to a surgical abortion, which contributed to a failed abortion" re-raises issues as to which the Department has already accepted RHS's plan of corrections and is medically inaccurate. On May 23, the Department accepted RHS's May 22 amended plan of correction. That amended plan of correction explained, in relevant part, that the Department's new interpretation of the 19 CSR 30-30.060(2)(D)—to require an additional, medically unnecessary pelvic exam—was textually and medically unsupportable, as well as a break from the Department's historic enforcement of the regulation. To be clear, we have never objected to performing a pelvic exam before a surgical abortion. The medically most appropriate time of that exam is immediately				

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	before the procedure, and for this reason, RHS performs a pelvic exam on the day of the procedure, not on the day of the patient counseling. As the American College of Obstetricians and Gynecologists has recently said: "While pelvic exams may be appropriate for patients with certain conditions, routine multiple pelvic exams for women seeking abortion care are unwarranted, invasive, and not supported by evidence." ACOG Stands With Clinicians Who Provide Reproductive Health Care (May 28, 2019), https://www.acog.org/About-ACOG/News-Room/Statements/2019/ACOG-Stands-with-Clinicians-Who-Provide-Reproductive-Health-Care. Because the Department appears to be re-raising the pelvic exam issue, we find it necessary to repeat our May 22, 2019 plan of correction: > [The Department's] change in position is surprising because it has long been RHS's practice to perform a pelvic examination in the context of surgical abortion on the day of the procedure, which is when it is medically appropriate and clinically relevant. And although the Department has inspected RHS annually for many years, it has never				

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	suggested that the examination be performed at a different time. This change is especially surprising because just last year, RHS's practices with respect to pelvic examinations were a focus of the Department's inspection. Specifically, last year the Department cited RHS for failing to ensure a pelvic exam was completed prior to a medication abortion. *See* Statement of Deficiency (survey date March 7, 2018). This "deficiency" was already an alteration of the Department's prior understanding of this regulation, because, as the Department is aware, prior to last year, the Department did not enforce the pelvic exam requirement for medication abortion because the requirement was written before approval of medication abortion in the United States, and it is medically unnecessary for that method of abortion. Because the Department changed its interpretation of this regulation last year and now requires a pelvic exam prior to medication abortion, and because RHS's physicians are not willing to impose on patients an invasive exam that is not medically appropriate in the				

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	context of medication abortion, we currently are not providing medication abortion to patients in Missouri. Most relevantly here, however, in multiple exchanges with RHS over the supposed deficiency for not providing a pelvic exam prior to a medication abortion, the Department at no point indicated when this exam would have to be performed other than prior to the abortion procedure (in either the medication or surgical abortion context). In now taking the position that the pelvic exam cannot be performed on the day of the abortion, the Department has expressed the concern that this timing "does not "meet[] the purpose of the requirement, which … includes 'detecting factors which could influence the choice of the procedure.'" This concern is unwarranted. Putting aside that as a result of the medically unnecessary pelvic requirement medication abortion is not available in Missouri (and at any rate is not an option after 10 weeks in pregnancy), a patient and physician can change the abortion method at any time prior to the abortion, in the				

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	exceedingly unlikely scenario that a pelvic exam reveals a reason to do so. At any rate, the primary information needed in determining the options that may be available to the patient is gestational age, which in current practice is determined not by a pelvic exam but by an ultrasound examination and medical history. In addition to determining which procedures the patient qualifies, hemoglobin testing and information on patient preference is considered in determining the choice of procedure. Without significant findings in the above listed evaluations, a pelvic exam provides no additional information that would influence the choice of procedure. The function of a pelvic exam in the abortion context is not to aid in determining type of procedure, but rather to inform the procedural approach in those choosing aspiration abortion. In this context the pelvic exam is critical to determining uterine size and position. Because information obtained from a pelvic examination might change from one day to the next (e.g., the patient's comfort level may change or her				

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	uterus may shift), physicians perform the pelvic exam immediately prior to the surgical procedure so that the information is relevant and not stale. Consequently, the information learned from a pelvic exam is most pertinent immediately prior to the abortion and not days before the procedure. The pelvic exam is also most appropriately done on the day of the abortion procedure in an effort to minimize the occurrences of invasive interventions. Pelvic exams, even in medically indicted situations, are not viewed as pleasant. Indeed, the American College of Obstetricians and Gynecologists has observed there is data to suggest that in asymptomatic patients, it is allowable and even preferable to defer pelvic exams during routine gynecologic visits. ACOG Committee Opin. No. 754 (Oct. 2018), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/The-Utility-of-and-Indications-for-Routine-Pelvic-Examination. Minimizing the number of pelvic exams, specifically restricting them to instances in which there is				

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	clear medical benefit, is important for all patients but especially for those who find vaginal exams particularly distressing, including because they have experienced sexual or other trauma. * * * Although RHS's practice were consistent with the regulation as written and current medical practice, in order to resolve the issue promptly, RHS revised its policies to require the additional Department-mandated pelvic exam "on the same day the patient receives the state-mandated information, at least 72 hours before the abortion." Despite the fact that this requirement is not supported by medical literature and stands to harm Missourians, and despite that the patient education day does not involve invasive medical procedures and that the patient will have the identical pelvic exam on the day of her abortion, which is the time it is medically appropriate, we previously made this concession so that Missourians can continue accessing abortion in their home state. The Department accepted this plan of corrections. The Department now nevertheless appears to be again raising the same episodes of patient care—which pre-date the plan of corrections the Department				

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	accepted—as new deficiencies. In the time RHS has provided the additional, medically unnecessary pelvic exam on the patient education day, it has become clear that forcing patients to have an additional, medically unnecessary pelvic exam is even more harmful, traumatic, and stigmatizing for patients than we anticipated. The additional invasive exam forces physicians to make an impossible choice between a patient-centered practice grounded in sound medical ethics and evidence or any providing care at all. Planned Parenthood is dedicated to providing our patients with high-quality health care—care that is respectful and nonjudgmental—and we have done so for decades. A fundamental attribute of quality care is patient-centeredness, which means "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Board on Population Health and Public Health Practice; Committee on Reproductive Health Services: Assessing the Safety and Quality of Abortion Care in the U.S., Washington (DC): National Academies Press				

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	(US); 2018 Mar. We believe continuing to force an additional invasive and uncomfortable pelvic exam on patients on the patient education day, when it is not medically indicated, and when the patient will have the identical exam on the day of her abortion procedure, is not patient-centered; it is disrespectful and dehumanizing, and contrary to our mission. This is true for all our patients, but especially for survivors of sexual trauma and for minors having their first pelvic exam. And for these reasons, unless medically indicated, we will no longer require patients seeking a surgical abortion to undergo a pelvic exam on the patient counseling day, which the State requires be at least 72 hours before the procedure. The Department also inaccurately suggests that a finding from the pelvic exam conducted by Staff F on Patient #1 was erroneous and contributed to the failed medication abortion. As RHS has previously explained, unless medically indicated, a pelvic examination is medically unnecessary before medication abortion because it provides no useful information relevant to that procedure. ACOG, as noted above, agrees. To be clear, there is no basis for the Department's conclusion that Staff F made an inaccurate finding on				

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	the pelvic exam, and indeed, the attending physician documented a similar finding on the supervision note from that day. It is unclear what basis the Department (which was not present to witness the pelvic exam) could have for presuming that the existence of a known complication is evidence that the pelvic exam was not done properly. Moreover, to suggest pelvic exam findings in any patient could predict the success or failure of medication abortion is scientifically unsupported. *See* Chill HH, Malyanker N, Karavani G, Haj-Yahya R, Herzberg S, Bahar R, Shveiky D, Dior UP. Association between uterine position and transvaginal misoprostol treatment for early pregnancy failure. J Obstet Gynaecol Res. 2018 Feb;44(2):248–252. doi: 10.1111/jog.13512. Epub 2017 Nov 2. PubMed PMID: 29094502. To the extent the Department suggests an inaccurate finding led to the abandoned surgical abortion attempt, it is similarly wrong. The Department's premise—that had the pelvic exam been completed on the day of consent it would have been known that the patient would not have had a successful first attempt at aspiration—is equally false. Uterine position is not a contraindication to either medication or aspiration abortion. All patients undergoing aspiration abortion				

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	have an instrument called a tenaculum placed on the cervix. The tenaculum allows for traction on the cervix which in turn changes the direction of the uterus from its resting place identified on the pelvic exam to a more midline position. Thus, for most, the cervix and uterus are not in the same position during the aspiration procedure as it is on pelvic exam. Amy Garcia, UPDATE: MINIMALLY INVASIVE SURGERY, OBG Manag. 2009 April;21(4):22–34, https://www.mdedge.com/obgyn/article/66235/update-minimally-invasive-surgery/page/0/1. As the record of Patient #1 shows, during the first surgical abortion attempt, Staff F (a fourth-year OB/GYN resident) documented her uterine position as "ant," or anteverted. This finding was confirmed by Staff A (an OB/GYN and fellow) who documented "Uterus anteverted but retroflexed." Staff E (attending OB/GYN physician), who also personally attempted the surgical procedure, noted that the patient has a "very acutely retroflexed uterus and the pregnancy was at the fundus." All three physicians documented consistent findings, and there is no basis for the Department to conclude they were erroneous. Because of the acute retroflexion of the patient's uterus, the cervix required substantial traction and use				

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	of multiple imaging and positioning modalities to maintain a safe attempt at evacuation. The patient underwent the first attempt at aspiration with local anesthesia and a paracervical block (i.e., a local anesthetic). As Staff E noted "the angle and traction on the cervix was quite uncomfortable for the patient." With all of this considered, the procedure proved to be incredibly uncomfortable for the patient and with a safe alternative in medication, together, the care team and the patient opted to change the treatment plan. It is appropriate clinical care to modify the course of treatment when it becomes clear that the procedure originally contemplated (in this case, aspiration) is not optimal for the patient, and to revisit with the patient her original decision that she preferred an aspiration abortion. Moreover, contrary to the Department's repeated characterizations this is not a "failed abortion." The patient did not leave the facility believing that her pregnancy termination was complete, but instead was counseled extensively about the risks and benefits of the new approach, and opted to proceed with a medication abortion. Over the next two days, the patient completed the standard medication abortion protocol, including directly observed therapy with mifepristone given by				

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	Staff E and self-administered misoprostol. The patient returned [redacted] later for standard follow-up care. At this time, she was noted to have an ongoing pregnancy, which is a known risk of medication abortion. Staff E performed a pelvic exam and found the uterine position "post," or retroverted. Staff E again noted the uterus was "[r]etroflexed." (Note: The Department incorrectly states this note is from an unknown author, when in fact it is signed by Staff E.) The Department apparently believes the anteverted finding by Staff F must have been inaccurate because of the retroverted finding three days later by Staff E. This alleged deficiency exemplifies the Department's lack of understanding of medicine—and basic female anatomy—and further demonstrates the inappropriateness of the Department purporting to dictate the standard of care applicable to physicians as it relates to abortion care without reference to any statutory or regulatory requirement or recognized standard of care. As RHS stated in the May 22 amended plan of correction, a pelvic examination on the informed consent visit, which necessarily must be at least 72 hours before the procedure, would not have prevented either the failed abortion Patient #1 experienced or the unsuccessful first attempt at				

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	aspiration. Chill HH, Malyanker N, Karavani G, Haj-Yahya R, Herzberg S, Bahar R, Shveiky D, Dior UP. Association between uterine position and transvaginal misoprostol treatment for early pregnancy failure. J Obstet Gynaecol Res. 2018 Feb;44(2):248–252. doi: 10.1111/jog.13512. Epub 2017 Nov 2. PubMed PMID: 29094502. As we previously stated, pelvic examinations are done immediately prior to the procedure to provide information relevant to the procedural approach. Most obvious is the fact that the increasing gestation has substantial impact on the position of the uterus. As the State of Missouri has placed many barriers to patients accessing abortion care, quite frequently patients return for completion of care well beyond the 72 hours that are mandated. The growing gestation most certainly changes the position during that interval time. There are in fact a multitude of factors that contribute to uterine position that we will lay out below, and that Staff E explained during her May 28, 2019 interview. The Department has rejected this explanation as "insufficient." The uterus is shaped like an upside-down pear and sits within the pelvis. There are four main parts of the uterus: fundus, corpus, isthmus, and cervix. The fundus is the uppermost part (and connects to the				

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	ovaries via fallopian tubes), the corpus is the body, the isthmus (as the name suggests) is the narrow part that connects the corpus to the cervix, and the cervix connects the uterus to the vagina. For a diagram, please see https://www.healthline.com/human-body-maps/uterus. "The uterus is supported by several ligaments including the utero ovarian ligament, round ligament, broad ligament, cardinal ligament, and uterosacral ligaments. It is further supported (inferiorly) by the pelvic diaphragm, urogenital diaphragm, and perineal body. The uterus may naturally lie in different positions such as anteverted/retroverted, anteflexed/retroflexed, or midline, and it may be rotated (especially during pregnancy). The uterus most commonly lies in an anteflexed and anteverted position in 50% of women." Sosa-Stanley JN, Peterson DC. Anatomy, Abdomen and Pelvis, Uterus. [Updated 2019 Feb 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470297/. Uterine size, shape, and position are not permanently fixed and are affected by many factors, including but not limited to pregnancy, full bladder, constipation,				

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	position on the exam table, pelvic floor musculature, timing in the menstrual cycle, and medications. This should be obvious; indeed, a quick internet search demonstrates this even to lay individuals. For example: "The most common position of the uterus is anteverted (cervix angles forward) and anteflexed (body is flexed forward). The position of the uterus in the adult is liable to considerable variation, depending chiefly on the condition of the bladder and rectum. When the bladder is empty the entire uterus is directed forward, and is at the same time bent on itself at the junction of the body and cervix, so that the body lies upon the bladder. As the bladder fills, the uterus gradually becomes more and more erect, until with a fully distended bladder the fundus may be directed backward toward the sacrum." https://radiopaedia.org/articles/uterus?lang=us Several of these factors are relevant to Patient #1: 1. The gestational age of the pregnancy. This patient began care at [redacted] based on ultrasound and completed care at [redacted] based on ultrasound. As previously noted, the increasing gestation has substantial impact on the position of the uterus. 2. Exposure to medications. This patient received both				

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	mifepristone and misoprostol as part of her medication abortion. Mifepristone is a progesterone receptor antagonist that initiates the breakdown of the endometrium and implanted embryo. Misoprostol is a prostaglandin, which causes uterine contractions and cervical ripening. These medications have substantial impact on both the cervix and uterus—not only in changing the architecture of the organs but also, if not completely expelling the pregnancy, in moving it to a lower position in the uterus. (As Staff E noted after the first surgical abortion attempt, "the pregnancy [was] at the fundus."). 3. Patient comfort. As RHS previously expressed, pelvic exams are invasive and they are not comfortable. In fact, because the position of the uterus in part relies on the pelvic floor musculature, anticipation of pain or experienced pain can cause tensing of those muscles, changing in the position, or resulting in inability to fully appreciate the true position. On the day of procedure—when pelvic exams are helpful—patients receive local anesthetic and, if desired, oral or intravenous sedation to reduce discomfort during the abortion procedure; this also has the effect of reducing discomfort during the pelvic exam. (This patient received intravenous sedation on				

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	the day of her second aspiration attempt, was comfortably sedated throughout, and thus had an uncomplicated aspiration without difficulty.) The Department cites a 1997 textbook and an article from 1978 apparently in an effort to show that errors in diagnosis from pelvic examinations occur. That errors occur in medicine does not mean Staff F made an error here. Moreover, the latter source focuses on failed surgical abortions, but as discussed above Patient #1 did not have a failed *surgical* abortion; rather, she made an informed decision to stop an attempted surgical abortion and opted instead for a medication abortion (which did fail later). (Note: The Department is in receipt of the complication report for the failed medication abortion for Patient #1, although it appears to have lost the original form that was sent by certified mail. See Tag L1129, below.) For these reasons, the Department's belief that the failed medication abortion and/or the abandoned surgical abortion attempt could have been prevented if the pelvic exam had been done on the day of the patient education visit instead of the day of the abortion, or in the alternative that there was some issue with how the pelvic exam was done that rendered it inaccurate, is as medically unsupported.				

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	There is no basis for the Department to substitute its unsupported judgment for the clinical judgment of the physicians who provide direct patient care and who are experts and specialists in abortion care. Finally, we note that the Department takes issue that Staff A and Staff F refused to be interviewed by Mr. Koebel (who is not a physician). The Department does not explain, nor is it apparent, what information these trainees could have provided. The patient's record provides all the information the Department needed, but even if that were not enough, their attending physician, Staff E, was interviewed. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. (2) Despite that the tissue exams performed by the RHS-affiliated physicians and the contracted pathology lab that showed consistent results, the Department cites RHS for failing to ensure the accuracy of the tissue exams to ensure a complete abortion. At the outset, we note failed abortion (meaning, although it was expected the pregnancy has been				

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	terminated, the pregnancy remains ongoing) is a rare but known outcome of surgical abortion. Indeed, in the 1978 article the Department cites, providers did a gross exam of tissue, yet still had some failed abortions (0.071%). In other, more current published research, the rate of failed abortion ranges from 0.05% to 0.2%, up to 2.3%. Doan Ireland, Luu & Gatter, Mary & Y. Chen, Angela. (2015). Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester. Obstetrics & Gynecology. 126; Paul ME, Mitchell CM, Rogers AJ, Fox MC, Lackie EG. Early surgical abortion: efficacy and safety. Am J Obstet Gynecol. 2002 Aug;187(2):407–11. PubMed PMID: 12193934. At RHS, in 2018, we had three known failed surgical abortions out of approximately 2500 surgical abortions, or a rate of 0.12%—well within the published range. Despite this, the Department latches onto two cases of this rare but known complication to falsely suggest that that RHS has a widespread problem of failed abortion that supports a deficiency finding. This is simply unsupported. Patient #2 had a surgical abortion at [redacted] based on ultrasound. At that gestational age,				

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	some but not all fetal parts may be seen in a gross examination. It is for this reason that Planned Parenthood's evidence-based Medical Standards and Guidelines, as reflected in RHS policy 1.1.17, provide that the tissue examination must include identification of (1) villi and membranes, (2) in pregnancies of 10 to 13 weeks gestation, some fetal parts, and (3) in pregnancies ≥ 13 weeks gestation, all fetal parts. As the record shows, Staff B identified villi, membrane/sac, and some fetal parts. This is supported by the independent tissue exam performed by the contracted pathology lab. The lab found villi consistent with [redacted] gestation, fetal parts, placental membrane, and decidua. It is virtually impossible to evacuate some fetal parts during the procedure yet leave the pregnancy undisturbed. For that reason, during the quality assurance review, Staff I, RHS's co-medical director, reasoned "most likely a pregnancy missed of a twin." The Department rejects this explanation as "insufficient." But as the record reflects, the patient had a second surgical abortion at [redacted] based on ultrasound. At that gestational age, as noted above, all fetal parts should be identifiable in a gross exam. That was the case here. Staff B identified villi,				

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	membrane/sac, and all fetal parts. Likewise, the pathology lab found villi consistent with [redacted] gestation, fetal parts, placental membrane, and decidua. The physician who performed the second pathological examination was different from the one who performed the first. It would be impossible to remove some fetal parts and then later find the fetus had all parts, unless there was a twin (multifetal) pregnancy. Given the limitations of ultrasonography on obese patients (such as Patient #2 who had a BMI of [redacted]), it is possible the ultrasound done at the initial presentation for informed consent might have missed such a diagnosis. Paladini, D. (2009), Sonography in obese and overweight pregnant women: clinical, medicolegal and technical issues. Ultrasound Obstet Gynecol, 33: 720–729. doi:10.1002/uog.6393. Put simply, the Department disagrees with the findings of three licensed, board-certified, and fellowship trained physicians. And its only basis for disagreement is the 1978 article, which discussed 46 patients with failed surgical abortions and did not note that any involved twin pregnancies (though it is unclear how the article's authors could have known if there was an undiagnosed twin pregnancy). To again				

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	state the obvious, even if none of the patients in that study had a twin pregnancy does not mean Patient #2 also did not have a twin pregnancy, because she clearly was not a subject in that study. Twin pregnancies are common. According to the CDC, the twin birth rate in the U.S. is 33.3 twins per 1000 births. https://www.cdc.gov/nchs/fastats/multiple.htm Patient #3 had a surgical abortion at [redacted] based on LMP. Staff A documented villi and membrane/sac on the gross exam. The contracted pathology lab also found villi consistent with [redacted] gestation, placental membrane, and decidua. Despite these consistent findings, the Department alleges Staff A's tissue exam was inaccurate. The gross and microscopic examination conducted by a trained, independent pathologist confirms Staff A made no error. Presence of membrane/sac on the initial gross exam and final pathological exam, moreover, does not necessarily ensure a complete abortion; rather, all that can be verified is that some tissue was evacuated. Gross tissue exam is imperfect and even highly trained physicians and pathologists are not always able to accurately confirm a completed abortion from a gross tissue exam, particularly at earlier gestations (as with Patient #3). For instance, in one study, 1% of				

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	pregnancies were ongoing even though both the abortion provider and a pathologist found products of conception in the aspirates. Paul M, Lackie E, Mitchell C, Rogers A, Fox M. Is pathology examination useful after early surgical abortion?. Obstet Gynecol. 2002 Apr;99(4):567–71. PubMed PMID: 12039112. Staff E stated the same in her May 28, 2019 interview. The same study found that approximately 90% of surgeons and pathologist correctly found products of conception during the tissue exam among patients with complete abortion. Conversely, both surgeons and pathologists were poor at identifying an incomplete or failed abortion, with pathologists faring worse than the abortion provider (57% vs. 22%). Similarly, the 1978 article the Department cites identified shortcomings of the gross examination. We note the Department has indicated that CMS has cited the contracted pathology lab and that the lab has corrected all cited deficiencies. The Department's note does not indicate any deficiencies could have or did affect the results of any tissue exams. But even if any deficiency could have had any effect on any results, it is unclear what the Department believes RHS could have done about that.				

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	If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. (3) The Department cites RHS for failing to meet a newly created and never before articulated requirement to ensure there was communication with the pathology lab after the discovery of a failed abortion. As discussed above, the alleged deficiency is not based on any legal requirement—and the Department cites none. As discussed above, Patient #2 did not experience a failed surgical abortion. Patient #3's pathology examination did not yield any unexpected results. In fact, the initial gross exam was consistent with the later pathology exam. As RHS policy provides: "Pathology examinations that yield unexpected results with be reported to an abortion provider clinician by phone within 24 hours." Thus, no trigger occurred that would make communication appropriate. And Staff I, RHS's co-medical director, confirmed in his May 28, 2019 interview that it was a "regular occurrence" for there to be communication between him (or the lead clinician) and the pathology lab regarding unexpected results.				

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	(As noted above, pathologists are no better at finding evidence of an incomplete or failed abortion during an tissue examination, and for that reason, the requirement that all tissue be sent to pathology is irrational, as well as burdensome.) Despite this, in a good-faith effort to resolve this deficiency, RHS will notify its contracted pathology lab each time it discovers a failed abortion, even though the pathology report showed membrane/sac and/or fetal parts. RHS will incorporate this requirement into its quality assurance protocol. (4) The Department falsely accuses RHS of failing to ensure the prompt followup with Patient #2 when she complained of continuing pregnancy symptoms. But the Department's description omits that RHS appropriately followed up with Patient #2. Twenty minutes after the patient called stating her concern she believed she was still pregnant; a nurse returned her call (at [redacted]). The nurse offered her a follow-up appointment two days later, on [redacted], which the patient accepted. The patient did not show but instead returned on [redacted]. As Staff I stated in his interview, "Patients have complicated lives…. I do not know why a patient would not come back for [redacted]." RHS				

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	did not fail to ensure prompt follow-up. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. (5) The Department cites RHS for failing to ensure informed consent was obtained from two patients prior to "new surgical abortions following failed abortions." To be clear, Patient #2 and #3 both received and signed procedural consents related to their treatment for an ongoing pregnancy. These documents were signed on the day of the patient's follow-up procedure and are in addition to the consents obtained for the first abortion attempt that failed. In particular, each patient signed an informed consent document as well as Information for Informed Consent sheets, which detail the requested procedure and its risks and benefits. Each patient was also given written post-care instructions. Moreover, each record also reflects that the physician counseled the patient on the second procedure and answered her questions; each patient demonstrated an understanding and that she was prepared for the abortion. All this information, including the signed consents, are in the patient's record. Thus, it is unclear what basis the Department could have to find that these patients did				

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	not adequately consent to their follow-up procedures. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. The Department, moreover, references a book published by the anti-abortion organization the deVeber Institute, whose namesake founded Defense of the Unborn and was the former national president of Alliance for Life in Canada. Moreover, the book's author Elizabeth Ring Cassidy is described by Our Lady Seat of Wisdom College, at which she is an Adjunct Professor, as "published widely in the areas of Life issues." This further demonstrates the Department's commitment not to medicine and fact but to a political agenda to end abortion. (6) For two patients who had failed abortions, the Department cites RHS for failing to ensure the informed consent process included a second state-mandated 72-hour waiting period. If the Department's position is that a patient who experiences a failed abortion must delay her care another 72 hours, thus forcing these patients to wait a total of 144 hours, or 6 days, before obtaining an abortion, this position is unsupported by statute and would be deeply troubling from a patient care perspective, including because				

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	while abortion is very safe the risks increase with gestational age. Section 188.027.6, RSMo. provides: The physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of: (1) The immediate and long-term medical risks to the woman associated with the proposed abortion method including, but not limited to, infection, hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion; and (2) The immediate and long-term medical risks to the woman, in light of the anesthesia and medication that is to be administered, the unborn child's gestational age, and the woman's medical history and medical				

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	conditions. RHS complied with this provision when it counseled Patients #2 and #3 (and all other patients) on day one of the abortion process (the patient education visit). After counseling the patient on the proposed method(s), physicians counsel the patient on the risks and benefits, including infection, hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion, as required by 188.027.6. The complications a patient is at risk for from surgical abortion are the same regardless of gestational age, though the degree of risk increases with gestational age. Physicians advise patients of this fact. Physicians, moreover, counsel the patient that the physical risks increase with gestational age. Patients are also given the Department's informed consent booklet. As required by section 188.027, RSMo., that booklet must "describe the various surgical and drug-induced methods of abortion relevant to the stage of pregnancy, as well as the immediate and long-term medical risks commonly associated with each abortion method including, but not limited to, infection, hemorrhage, cervical tear or uterine perforation, harm				

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	to subsequent pregnancies or the ability to carry a subsequent child to term, and the possible adverse psychological effects associated with an abortion." § 188.027.1(3), RSMo. The booklet also states: "The later in pregnancy the abortion is done, the more complex the procedure and the higher the risk." Thus, Patients #2 and 3 received all required information at their patient education visits. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. (7) The Department cites RHS for failing to ensure the appropriateness of nursing care based on a nurse's instruction to perform a self-fundal massage, despite having no authority over nurses and citing no evidence that the instruction was inappropriate. That is because the Staff J gave an appropriate instruction. Patient #4 called the day after her procedure complaining of bloating. When Staff J returned her call, the patient stated the bloating had resolved. Staff J then advised the patient do a "fundal massage and call *for heavy bleeding*," to call if "pain unrelieved by massage and OTC meds," or to call if she had a "fever." The Department does not say why this instruction was inappropriate. As the Department				

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	summarized, Staff J stated in her April 24 interview, "[f]undal massage is appropriate direction for a patient complaint of bleeding and cramping." This is consistent with standard of care and with the written instructions provided to abortion patients. In RHS's "Taking Care of Yourself After an In-Clinic Abortion," patients are advised that "[m]assaging your lower abdomen may also help" with cramps. Moreover, there is abundant research documenting the utility of uterine massage to manage bleeding caused by uterine atony, including at lower gestational ages. Ipas, *Clinical Updates in Reproductive Health: Managing postabortion hemorrhage*, https://www.ipas.org/clinical-updates/postabortion-care/managing-hemorrhage (last reviewed Dec. 19, 2018); Nat'l Abortion Fed., Clinical Policy Guidelines for Abortion Care (2018), https://prochoice.org/resources/clinical-policy-guidelines/; Soc'y of Family Planning, Clinical Guidelines: Management of postabortion hemorrhage, 87 Contraception 331 (Nov. 2012), https://www.contraceptionjournal.org/article/S0010-7824(12)00954-7/pdf. It also bears noting that performing a self-fundal massage is not harmful, even if it the benefit may be limited in some circumstances.				

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	The appropriateness of the instruction is evidenced by the fact the patient returned to the facility [redacted] because she "developed post op pain." The ultrasound revealed intrauterine debris, suggesting retained products of conception and/or blood. Indeed, the aspirates contained dark clots. It is concerning that the Department staff issuing this deficiency is apparently unfamiliar with the nature of fundal massage, as indicated by Mr. Koebel asking whether it involves placing a hand inside the patient's vagina. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. (8) The Department appears to suggest that RHS failed to ensure an abortion was planned in a safe environment for Patient #12 and that the appropriate risks and benefits were not conveyed to her. As should be clear from the record, the patient did not have an abortion or attempted evacuation at RHS. Yet, the Department accuses RHS of jeopardizing the patient's life. Not only is it untrue, but this patient's circumstance demonstrates why abortion should				

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	remain accessible. Patient #12 had a termination for medical reasons. She was evaluated at Washington University School of Medicine on [redacted] 2019, after being referred from out of state secondary to limited access in her home state and a known placenta previa in the setting of a history of cesarean. As is standard in this instance, the evaluation included a transabdominal and transvaginal ultrasound performed by an expert in obstetric and gynecologic diagnostic ultrasonography because of a "[s]uspected uterine abnormality, [p]revious cesarean delivery;" this ultrasound was done at Washington University (not at RHS). The results were interpreted by one of the University's most senior and experienced physicians, a board-certified OB/GYN with a fellowship in ultrasound and medical genetics and who is a full professor in OB/GYN within the Division of Maternal-Fetal Medicine and Ultrasound, as well as Radiology. The ultrasound revealed anterior placental previa; it did not suggest findings concerning for placenta accreta spectrum, and indeed, "there [were] no highly suspicious findings for such." As Staff H noted: "[Patient #12] had formal U/S at WashU which did not show [evidence of] morbidly adherent placenta." Characteristics that are typically				

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	evaluated when there is concern for abnormal placentation include vascular lacunae, loss of the hypoechoic zone normally visualized between the placenta and myometrium, myometrial thickness, and any abnormalities of the uterine serosa and bladder interface. Berkley EM. Prenatal diagnosis of placenta accreta: is sonography all we need? J Ultrasound Med 2013; 32:1345–50; Comstock CH, Bronsteen RA. The antenatal diagnosis of placenta accreta. BJOG 2014; 121:2. These characteristics, along with use of Doppler flow, were assessed in this case, and previous studies have noted a sensitivity of 90.72% and specificity of 96.94% with this approach. D'Antonio F. Prenatal identification of invasive placentation using ultrasound: systematic review and meta-analysis. Ultrasound Obstet Gynecol 2013; 42:509–17. It is important to understand that definitive diagnosis of accreta spectrum disorders of the placenta can only be made on histologic evaluation of a hysterectomy specimen (i.e., in the event that the birth or abortion resulted in life threatening bleeding requiring surgical removal of the uterus), meaning that prior to a birth or abortion, providers use imaging tools to best predict the safest care plan. With an ultrasound that did not demonstrate any				

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	concerning findings for placenta accreta spectrum, the patient was then counseled at Washington University on the risks and benefits of continuing to term, as well as the risks and benefits of termination. The record reflects: "We discussed that her underlying medical conditions including anterior placenta previa would increase her risks associated with the procedure, but that the risk of continuation of pregnancy is greater than proceeding with termination." Notably, the patient was counseled on the potential morbidity associated with such placental accreta spectrum disorders, as well as the reality that the risk of morbid outcomes increases as the pregnancy progresses. The patient understood all of these issues and made a clear and informed decision to proceed with abortion. The clinical team, using all of the available evidence and in consultation with the patient, made the assessment that her abortion could be safely provided in an outpatient setting. The patient signed the appropriate consents, which are contained in the record. Given the patient's gestational age, the patient required completion of care over two days. On the first day, the patient underwent placement of dilators, during which the clinical team noted more bleeding than was standard for dilator placement. Blood loss				

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	was estimated at 200cc, which is not considered "hemorrhage." As is appropriate with an evolving clinical situation, the care team reassessed the situation when presented with new clinical information and opted to complete the patient's care in the hospital setting. A vaginal pack was placed, and the patient was transferred to the hospital via EMS in stable condition. During the transfer, the patient remained awake and oriented and had stopped bleeding by the time of arrival at BJH, 1.1 mile from the RHS location. Despite the Department's assertion to the contrary, the patient's bleeding was neither massive nor uncontrolled. No less than four clinicians, including Staff O, Staff N, Staff H, and a nurse practitioner attended to Patient #12 while at RHS. It is flatly inaccurate to suggest that as a result of the care provided at RHS, the patient was found "critically ill and suffering from shock, on pressors (drug for treating hypotension) and suffering massive blood loss." The clinical team identified the higher level of care needed and changed plans accordingly. This demonstrates the sound decision making of the RHS care team and the recognition to escalate this patient's care to a higher acuity setting as a result of the clinical picture after insertion of osmotic dilators.				

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	At BJH, with an evolving clinical picture, the patient was again counseled on the risks, benefits, and alternatives. In particular, the patient was again advised of the "increased risk to maternal health or life endangerment from placenta previa, history of cesarean section, and possible placenta accreta." The patient verified her desire to proceed with evacuation, and underwent that procedure several hours later under controlled circumstances. It is indisputable the BJH clinical team, including Staff H, took great care of the patient. Her fertility, and life, were preserved in large part because of the excellent clinical skills demonstrated by RHS's Staff H in both locations. Only with the benefit of hindsight does the Department suggest it was in error for the clinical team to consider providing an abortion for the patient at RHS, and it bases that suggestion on speculation that the patient had placental accreta. But as discussed, there was no ultrasound evidence suggesting placenta accreta found by the ultrasound specialist, and because the patient did not require hysterectomy, there is evidence to confirm such a diagnosis now. This patient's pre-op evaluation was completed in a manner consistent with standard of care and RHS and Washington University protocol. Given the available				

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	information it was completely appropriate for the care team at both Washington University and RHS to determine that RHS was the appropriate facility for the patient to receive care at. While the Department second guesses Patient #12's abortion because of the complications she experienced, it fails to consider the alternative: significant risk of maternal morbidity and even mortality. (The same circumstances that made her abortion higher risk also makes carrying to term and delivering higher risk on an order of magnitude.) Indeed, Missouri ranks 42nd in the nation for maternal mortality. It also fails to acknowledge its own role in limited hospital access to abortion care—specifically bans on private and public insurance from covering the service in nearly every circumstance, making hospital care financially impossible for most. Missouri women deserve better. For these reasons, no deficiency exists; to the contrary, RHS and Washington University provided high-quality care to a patient with a complex medical situation. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency.				

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L-1076	(1) RHS cooperated fully with the Department's investigation, providing *all* requested medical records and other documentation. RHS also made its own employees available for interviews with investigators. RHS's co-Medical Director, Staff I, and incoming Chief Medical Officer, Staff E, who also served as attending physicians supervising the training of the residents and fellows who declined to be interviewed, were also interviewed by the Department. Thus, there simply is nothing the Department is seeking to investigate that is not fully contained in medical records and documents already provided or which could not have been obtained by discussions with Staff E and Staff I. As the Department's counsel noted in court that it is not clear *how* RHS was supposed to compel interviews from residents who have not provided care at RHS's facilities since 2018 and who will not be providing such care in the future. As noted by the resident physicians' counsel, "The Residents are not currently rendering patient care at Planned Parenthood, nor will they do so in the future." *Reproductive Health Services of Planned Parenthood of the St. Louis Region v. Parson* (RHS v. Parson), 1922-CC02395, Non-Party Resident Physicians	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	N/A

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	Memorandum of Law in Support of Motion to Quash Subpoena and for Protective Order ("Resident Mot. Quash") at 5. This is particularly true where, as here, the unique criminal penalties associated with abortion laws in Missouri—which do not appear in analogous statutes concerning similar kinds of health care facilities—mean that any physician subjecting themselves to Department questioning may be placing themselves in personal jeopardy of being referred for criminal investigation. *See id.* at 6–8 ("The State … argues that physician interviews are standard for any licensing investigation, but this situation is hardly analogous to other license renewals. Clearly, the unique criminal penalties associated with abortion laws distinguish this investigation from a licensure application submitted by an ambulatory care center. It is disingenuous for the State to pretend that calculation has no relevance here."); *RHS v. Parson*, Motion of Non-Party Physicians "Staff A" and "Staff H" to Quash Subpoenas and for Protective Order ("Staff A/H Mot. Quash") at ¶ 21 (counsel unable to assess whether "testimony creates any personal jeopardy" for physicians). Moreover, as detailed in RHS's prior submissions the Department has already changed its				

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	interpretation of what is required to comply with the pelvic exam requirement, *see* May 22, 2019 Plan of Correction, and has similarly changed its interpretation of what is required for residents and fellows training in abortion care under the supervision of an attending physician to comply with the requirements of section 188.027.6, RSMo., *see* May 28, 2019 Plan of Correction—and yet the Department asks to interview physicians about the care they provided under RHS's prior policies, despite that it has already accepted RHS's Plans of Corrections on these issues. Legal counsel for the physicians in question "asked repeatedly for information regarding the nature of the investigation, the State demurred, offering no substantive information about the inquiry. To be clear, it was the State's chosen strategy that prevented interviews with the Residents." Resident Mot. Quash at 7 (citing Exhibit G to the Aff. of William Koebel); *see also* Staff A/H Mot. Quash at ¶ 21 ("DHSS has refused to provide information to allow counsel for these physicians to assess whether their testimony creates any personal jeopardy for them."). And RHS has also further attempted to ensure the Department has access to any needed information by requesting				

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	written questions to which the physicians who declined to be interviewed could provide written responses, but the Department declined. While RHS has always cooperated with the Department's investigations, never in the past 10 years has any Department employee requested the kinds of audio-recorded, sit-down questioning with physicians that it has demanded during this investigation, let alone demanding to question physicians no longer affiliated with the clinic and in some particular order. *RHS v. Parson*, Petitioner's Reply Suggestions in Support of Petitioner's Motion for Temporary Restraining Order and Preliminary Injunction, Exhibit A, Declaration of David Eisenberg, MD, MPH at ¶¶ 5–10, 12–14. Generally, staff and physicians on site the day of an inspection will have short, informal conversations with inspectors, and then the Medical Director would engage in more substantive conversations concerning specific patients or an inspection summation. *Id*. RHS did just that during this investigation. Moreover, the Department lacks the statutory authority to compel RHS to produce testimony from third parties. Section 197.230.1 does not grant the Department the power to compel witness testimony.				

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	Had the General Assembly intended to confer such authority, it would have done so by statute. *See Bodenhausen v. Mo. Bd. of Registration for Healing Arts*, 900 S.W.2d 621, 622 (Mo. 1995) (state agencies "possess only those powers expressly conferred or necessarily implied by statute"); *cf. Angoff v. M & M Mgmt. Corp.*, 897 S.W.2d 649, 653 (Mo. Ct. App. 1995). Where the Legislature means to provide agencies with such power, it does so clearly and unequivocally. *See, e.g.*, §§ 334.100.2(4)(m)–(n) and 334.127, RSMo. (authorizing board of registration for the healing arts to issue subpoenas and take licensure action for failure to comply); §§ 335.066.2(6)(h)–(i) and 335.097, RSMo. (board of nursing, same); §§ 340.264.2(4)(*l*)–(m) and 340.280, RSMo. (veterinary medical board, same). Because the "legislature has elsewhere been fully capable of clearly articulating" this authority, it cannot be implied that the State possesses the power to compel interviews absent statutory language. *State v. Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc.*, 97 S.W.3d 54, 61 (Mo. Ct. App. 2002); *see also Wolff Shoe Co. v. Dir. of Revenue,* 762 S.W.2d 29, 32 (Mo. 1988) ("rule of statutory construction that 'the express mention of one thing implies the exclusion of another'"). Indeed, the Department's counsel admitted				

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	in court that the Department lacked the authority to compel interviews. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. (2) Despite that the Department already accepted RHS's May 28, 2019 plan of corrections on the same-physician issue, the Department spends at least five pages re-raising this issue, despite that all alleged deficiencies predate the plan of correction (including one that was specifically cited in the March 12 statement of deficiencies). For this reason, we find it necessary to repeat our May 28, 2019 plan of correction: > Under section 188.027.6 RSMo., "[t]he physician who is to perform or induce the abortion shall, at least seventy-two hours prior to such procedure, inform the woman orally and in person of" the information required in the statute. In its May 20, 2019 letter, the Department expressed concern that a supervising physician who "is merely present in the building without				

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	taking any active role in performing or inducing the abortion" is not a physician who performs or induces an abortion within the meaning of section 188.027.6. And as RHS had noted in its Plan of Correction, the Department previously advised the Circuit Court of Jackson County in its legal filings that "[w]hen there are two or more physicians who are substantially involved in performing or inducing the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 16, 2017). Additionally, as the circuit court found, under the Department's reading of the statute, "when multiple doctors are involved in the continuum of care before, during, and after a procedure that anyone of those physicians could provide the required information." Judgment/Order at 6, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 23, 2017). For these reasons and the other reasons set				

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	forth in its prior submissions, RHS believes its attending physicians have always been substantially involved in patient care provided through its residents and fellows. Nevertheless, in its May 22 Amended plan of corrections it agreed to revise its policies to require that when a fellow or resident is providing a procedure under supervision, the supervising physician will provide the state-mandated information required by section 188.027.6, RSMo., at least 72 hours prior and will be physically present in the procedure room during the abortion procedure. The Department has now rejected that Amended plan of corrections, stating that "mere physical presence is not enough" and also that the physician who provided the state-mandated information must play a "substantial and active role in performing or inducing the abortion" although it again does not define "substantial and active." To be clear, to the degree the Department is suggesting that an attending physician must be physically involved in providing patient care in order to meet this requirement, the Department's				

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	interpretation runs counter to accepted understanding by the larger medical education community of the relationship between attending physicians and the fellows and residents they supervise. Fellows and residents learn to practice medicine by performing hands-on procedures under the supervision of attending physicians, and it is well established that in this context the attending physician is understood to be actively involved in performing these procedures even if the fellow or resident is providing the hands-on care. Indeed, in prior litigation the Department specifically rejected the idea that it was unclear how the same-doctor requirement applied in the scenario of "*a medical resident working with a teaching physician to perform an abortion*" (emphasis added), stating that "Section 188.027.6 is not, in fact, ambiguous as applied to [this] scenario[]. When there are two or more physicians who are substantially involved in performing or inducing the abortion, any one of those physicians may satisfy section 188.027.6 by providing informed consent." Defendants' Suggestions in				

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	Opposition to Plaintiffs' Motion for Temporary Restraining Order at 22, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 16, 2017). Thus the Department clearly indicated that for purposes of Section 188.027.6, an attending physician who supervises a resident (or a fellow, presumably) in providing an abortion is sufficiently involved to be able to provide the state-mandated information required by Section 188.027.6. Moreover, while the Department now asserts that the Circuit Court "explicitly rejected the interpretation on which you now rely" by saying the Department's interpretation "expands the language of subsection 6 beyond its written words," this ignores that the Court went on to recognize that "[the Department's interpretation] is a reasonable interpretation of subsection 6." Judgement/Order at 6, Circuit Court of Jackson County, Missouri, Case No. 1716-CV24109 (Oct. 23, 2017). For these reasons RHS continues to believe its attending physicians have always been appropriately involved in patient care provided				

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	through its residents and fellows. Moreover, the Department's shifting interpretations of section 188.027.6, RSMo., seem to relate in no way to the Department's mission of promoting patient health and safety as the Department has never throughout this process suggested that any of RHS's prior or proposed practices with respect to section 188.027.6, RSMo. are inconsistent with the standard of care or have compromised patient health and safety. Nevertheless, in the interest of resolving this issue promptly and ensuring patients can continue accessing abortion in Missouri, RHS will revise its policies to require as follows: If RHS continues providing care through fellows and/or residents, it will ensure that the fellow or resident provides the information required by 188.027.6 RSMo, in the presence of the attending physician, and that both the fellow or resident and the attending physician document their participation in this process. In addition, as noted in our prior plan of correction, the attending physician and the fellow and/or resident will also both be present in the procedure room. In the normal course,				

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	the fellow or resident will be the primary or sole physician providing hands-on care to the patient during the abortion procedure. However, in any instance where in the medical judgment of the attending physician the attending physician should complete the procedure, the attending physician shall do so. In the alternative, RHS will ensure that both the attending physician and the resident or fellow play a substantial and active role in performing the abortion. RHS has concerns as to whether it is possible for multiple physicians to play a substantial and active role in providing an abortion procedure without interfering with good patient care, if by "substantial and active role" the Department means physical contact with the patient. This is especially true in the context of a short and straightforward procedure such as an aspiration abortion, which typically takes 3–5 minutes to complete. RHS also has concerns as to whether requiring this type of participation by the attending is consistent with the teaching and training function of a fellowship or residency through a teaching hospital.				

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	However, if RHS concludes that there is a way to do this consistent with providing meaningful training and without violating our ethical commitment to patient-centered care, we will advise the Department of revised protocols that provide (as the Department has directed) more specific guidance as to the substantial and active role the attending physician would play. The Department accepted the plan of corrections above, and RHS has since complied with its obligations under the plan of corrections. Indeed, there is no indication in the Statement of Deficiencies that the Department disagrees. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency. (3) The Department alleges RHS failed to submit a complication report for Patient #1's failed surgical abortion. As more fully discussed above, Patient #1 did not experience a failed surgical abortion. (Patient #1 did have a failed medication abortion. A report for that adverse event was submitted, even though the Department appears to have lost the report.) The patient did not leave the facility believing her pregnancy had been terminated. Indeed, the				

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	Department agrees there was an "abandonment of a surgical abortion." The 1978 article the Department cites also agrees that the definition of a failed abortion is one where the patient "has been subjected to an operative procedure for abortion only to be found at some later date still to be pregnant." Section 188.052.2, RSMo. requires a complication report only when "post-abortion care" has been provided. The change to a medication abortion is not "post-abortion care." RHS did not fail to submit a complication report for Patient #1. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency.				
L-1119	The Department cites RHS for failing to maintain accurate records, including accurate time and date, the identity of the physician providing a medication abortion, and the documentation of supervision. The bulk of this deficiency rests on the Department's confusion regarding the difference between the "encounter date" and the "current date" on each record. As explained by Staff C, and as evident by its name, "encounter date" refers to the date on which RHS had an encounter with the patient—i.e., the date the patient was seen at or had contact with RHS. The	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	N/A

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	"current date" reflects when the date on which the record was last locked. A locked record cannot be amended by a physician, because physicians do not have permissions to unlock a record. Rather, if a physician wishes to amend a record, she or he would need to submit an addendum to the record. This occurs, for example, when the patient calls the health center the next day with concerns or when a supervisory note is later added. The existence of these two separate times, which serve distinct purposes, does not indicate one or the other is inaccurate. The Department, moreover, alleges Patient #1's record is inaccurate because it doesn't accurately identify the physician who provided the medication abortion. As the record for Patient #1 shows, Staff E provided the medication abortion. That is shown by the notation: "Mifepristone administered to patient in clinic at [redacted] under observation by [Staff E]." Moreover, Staff E signed the Mifeprex agreement with the patient and the Department's Induced Termination of Pregnancy form. It is not true Staff I provided the abortion or otherwise administered any medications to the patient. The Department misreads the record to state that Mifeprex was "'administered to pt. in clinic' by RHS Medical Director, Staff I." In fact, the record				

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	notes that the Mifeprex was "ordered by" Staff I. As Staff E stated in her interview, "As the Medical Director, [Staff I] would be the one for whom the medication is ordered [] for the clinic, so he would be [] dispensing to me who was the person who administered the medication." The Department also cites RHS because one record does not include a procedure end time. The Department references no obligation on the part of RHS to include procedure start or end times in the record. To remedy any misunderstanding, RHS will work with its EHR system vendor to ensure that the times and dates of entries will correspond to the current time (and not the encounter date). Similarly, all documents scanned into the record will be annotated or marked with the current time and date. Because changes to the technology may take time, RHS staff will manually note the date and time and personnel in all entries until the appropriate changes can be made.				
L-1129	Incredibly, the Department cites RHS for failing to submit a complication because the Department is unable to find the report in its records, despite that the Statement of Deficiencies reflects that the Department	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	N/A

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ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	has been shown a copy of the complication report stamped as received by the Department. As the Department notes, Patient #1's record includes a complication report for a failed medication abortion. The Department has also observed that a copy of the report is contained within the bundle of reports sent to the Department and that a certified mail receipt was stamped as received at the Department. Despite all this, the Department cites RHS because it cannot find a copy of the report in the Department's records. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency.				
L-1169	The Department cites RHS for failing to review the appropriateness of the care provided in light of three failed abortions and failing to take action because of a "problem identified in the medical care provided at the facility, regarding the failed abortions." As discussed above, RHS's failed abortion rate is well within the rates in published literature, and services were provided to all three patients in accordance with the standard of care. There was, accordingly, no reason to suspect a problem (let alone a widespread one) that would warrant a systematic review and corrective action. RHS tracks all complications, including failed	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	See column B (CORRECTIVE ACTION)	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	abortion. As the SOD observes, the Clinical Quality Assurance Committee met and reviewed Patient #2's failed abortion, and concluded it was likely a missed twin pregnancy. The Department rejects the Committee's explanation as "insufficient." But as discussed above, the explanation is plausible and appropriate, and there is no basis for the Department to conclude that RHS's treatment of this patient failed to meet the standard of care. It also untrue Staff A performed at least two failed surgical abortions; as discussed above, one of these alleged failed abortions was in fact an abandoned surgical abortion attempt. If RHS determines that a physician has a pattern or practice that is concerning—either through the regular quality-assurance process or other means—the medical director would initiate a corrective training program to ensure the highest level of competency. No such pattern or practice exists. If the Department believes a deficiency has occurred, RHS requests clarification as to the nature of the deficiency.				

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

June 21, 2019

Ms. Cathy Williams
Interim President and Chief Executive Officer
Reproductive Health Services of Planned Parenthood of the St Louis Region
4251 Forest Park Avenue
St Louis MO 63108

RE: RHS License Application received May 16, 2019

Ms. Williams:

The Department is in receipt of RHS's Plan of Correction (POC), dated June 18, 2019, regarding deficiencies identified in a Statement of Deficiencies (SOD) sent to your agency on June 13, 2019. The POC for the following identified deficiencies is found to be acceptable to the Department:

- Under the deficiency cited at L-1069 for failure to ensure there was communication with the pathology lab after the discovery of failed abortions, RHS's POC indicated, "RHS will notify its contracted pathology lab each time it discovers a failed abortion, even though the pathology report showed membrane/sac and/or fetal parts. RHS will incorporate this requirement into its quality assurance protocol."

- Under the deficiency cited at L-1076 for failure to ensure the physician performing the informed consent was the same physician performing the abortion, RHS's POC indicated, "If RHS continues providing care through fellows and/or residents, it will ensure that the fellow or resident provides the information required by 188.027.6 RSMo, in the presence of the attending physician, and that both the fellow or resident and the attending physician document their participation in this process. In addition, as noted in our prior plan of correction, the attending physician and the fellow and/or resident will also both be present in the procedure room. In the normal course, the fellow or resident will be the primary or sole physician providing hands-on care to the patient during the abortion procedure. However, in any instance where in the medical judgement of the attending physician the attending physician should complete the procedure, the attending physician shall do so."

- Under the deficiency cited at L-1119 for failure to ensure medical records were maintained in a manner that accurately documents the time and date a record was created or amended and any specific amendments made to the record, RHS's POC indicated, "To remedy any misunderstanding, RHS will work with its EHR system vendor to ensure that the times and dates of entries will correspond to the current time (and not the encounter date). Similarly, all documents scanned into the record will be annotated or marked with the current time and date. Because changes to the technology may take time, RHS staff will manually note the date and time and personnel in all entries until the appropriate changes can be made."

For the remaining deficiencies, however, RHS proposed no corrective actions. Of note is RHS's reversal of a previously accepted corrective action regarding the performance of pelvic examinations as part of the preoperative health assessment under 19 CSR 30-30.060(2)(D). RHS's POC, submitted on May 22, 2019, and accepted by the Department, stated that "RHS [would] revise its policies to require that a pelvic exam must be performed on the same day the patient receives the state-mandated information, at least 72 hours before the abortion." RHS's June 18, 2019 POC retracts this corrective action by stating that "unless medically indicated, we will no longer require patients seeking a surgical abortion to undergo a pelvic exam on the patient counseling day, which the State requires be at least 72 hours before the procedure."

RHS's retraction revives a practice that conflicts with current Missouri law. As the Department has previously explained, under 19 CSR 30-30.060(2)(D), the findings from a pelvic examination must be used to "detect[ ] any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management." Because the information that a pelvic examination provides could influence the choice of the procedure, a pelvic examination must occur at that time under Missouri law. Because RHS's retraction contradicts 19 CSR 30-30.060(2)(D), the POC is unacceptable under current law.

Nevertheless, the Department believes that this issue may be resolved in a manner that promotes the Department's goals of quality patient care and safety. For that reason, the Department will promulgate an Emergency Amendment and Proposed Amendment to 19 CSR 30-30.060(2)(D) that will require the physician who will perform or induce an abortion to perform a pelvic examination at least 72 hours before an abortion unless—in the clinical judgment of that physician—such pelvic examination is not medically indicated at such time for that individual patient, with such a determination being documented in detail in the patient's medical record. Thus, the Department considers the pelvic-examination deficiency, with the other deficiencies set forth above for which proposed corrective actions were accepted, as deficiencies which do not impede RHS's licensure as an abortion facility.

There remain, however, numerous additional deficiencies detailed in the SOD that RHS did not respond to with proposed corrective actions. These deficiencies are serious and extensive, including but not limited to:

- Physicians who provided patient care at RHS—including three who are still credentialed to do so—have refused to cooperate with the Department's investigation and grant interviews to the Department regarding the patient care they provided at RHS. RHS primarily defends this noncooperation by asserting that the Department had no reason to interview those physicians because the Department was allowed to interview their supervising physicians and had access to the medical records regarding that patient care. But RHS does not contend that the supervising physicians have first-hand knowledge of the events under investigation, and RHS's own medical records—which at times state that a supervising physician was "present" for a procedure that did not occur until hours later, and regarding which a later interview revealed that "present" meant that the physician was merely "available in the surgical suite"—underscore the fact interviews are necessary because medical records do not always contain all accurate information regarding the care provided. The Department is charged with safeguarding the health of the people of Missouri. For those people who receive services from a licensed facility, the Department's

ability to interview facility staff and physicians who provide patient care to determine what occurred regarding that patient care and whether corrective actions are needed is indispensable to that duty.

- RHS contends that it can take no feasible steps to compel its physicians to be interviewed, and also indicates that—even if it could take these steps—it would not do so in any event. To be clear, RHS has provided no suggestion that it encouraged or even asked the physicians providing abortions and care at its facility to cooperate in the Department's investigation. This is consistent with RHS's general stance it assumed once the Department requested interviews—that it would provide the Department solely the information regarding patient care that RHS wishes to provide and solely on its own terms. The facility's refusal to cooperate undermines the Department's ability to conduct the investigation it deems necessary to safeguard patient's health.

- A critical area of investigation that could have been explored during a requested physician interview is what precisely occurred with respect to the failed abortion of Patient #2. RHS repeats its Quality Assurance finding that the failed abortion "'most likely'" was the result of a missed twin based on documentation of fetal parts in the medical record, but RHS reaches this conclusion only by crediting the gross-examination findings and discounting another medical record—an ultrasound conducted before the failed abortion that did not reveal a twin pregnancy. (Notably, RHS also claims that the medical records include all information the Department needs for its investigation except what the attending physicians—neither of which supervised Patient #2's physician—could provide.) RHS discounts the ultrasound based on a "possib[ility]" that the patient's obesity caused the twin to be missed. As explained in the Department's cover letter to the SOD, however, the Department was forced—as a consequence of the non-cooperating physicians' refusal to submit to interviews—to presume or infer that the physicians had no satisfactory explanation for the deficiencies cited. RHS also justifies its conclusions by relying on the gross examination of fetal parts, but it is precisely the accuracy of these gross examinations that the Department cites as deficient. Only Patient #2's physician could provide the most accurate explanation for what occurred based on that physician's direct observation and treatment of the patient, and that physician has refused to be interviewed. The same is true for the failed abortion following a gross examination of fetal tissue for Patient #3, whose physician also refuses to be interviewed. Because RHS refuses to accept these grave instances as deficiencies, the Department has no assurance that such instances would not be repeated.

- RHS insists that it was "completely appropriate" to plan an abortion for Patient #12 at RHS—in fact, it provided "high-quality care" to her—despite the fact that RHS would have been completely unprepared if the severe hemorrhaging that occurred at the hospital had happened at RHS's facility. RHS does not dispute that this potential for severe hemorrhaging was a serious possibility that presented grave threat to a patient safety. And RHS provides no satisfactory explanation for the decision to disregard guidance from ACOG, which indicates that the procedure should have been performed at the hospital. Patient #12's physician has refused to be interviewed, and RHS has taken no steps to encourage him or her to do so. Our SOD thus presumes that the physician has no satisfactory explanation for the deficiency, and RHS provides no satisfactory explanation and offers no corrective action. Without acceptable corrective actions for this and the other deficiencies related to Patient #12, the Department has no reasonable

assurance that the grave harm reflected in that case would not be repeated with respect to other patients seeking abortion care.

- Regarding the informed consent required under section 188.027 RSMo for the second abortions for Patients #2 and #3, RHS alleges that it complied with this statute. But when the Department requested all consent information for these patients during its investigation on May 8, 2019, RHS provided only informed consent for the first (failed) abortions. By refusing to accept these as deficiencies, RHS consequently offers no assurance that further deficiencies will not occur.

- For Patient #1, RHS contends that an attempted surgical abortion that cannot be completed does not constitute an abortion complication (specifically a failed abortion) because the patient did not leave the facility believing her pregnancy termination was complete. In other words, RHS contends that a failed abortion is not a failed abortion so long as the patient knows the abortion failed. This explanation is not plausible and contradicts RHS's own practice of filing complication reports for failed medication abortions, where the patient also knows the abortion has failed. RHS's refusal to consider this as a deficiency likely has resulted, and will result, in fewer diagnosed abortion complications being reported, which is contrary to section 188.055.2 RSMo. In addition, the Department did not receive a complication report for Patient #1's failed medication abortion. RHS also offers no assurance that the inaccurate pelvic examination completed by a medical resident—which among other things documented the clearly pregnant patient's uterine size as less than 6 weeks—would be addressed by any plan of correction. Again, the physician fellow (who remains credentialed at RHS) and the medical resident who were present during the initial treatment of Patient #1 have refused to be interviewed, and RHS has refused to take any steps to encourage them to cooperate.

Further discussion of the RHS's responses to the numerous remaining deficiencies detailed in the SOD is not necessary. Summarily, except for those deficiencies noted at the outset of this letter, RHS fails to identify any corrective measures it will implement or identify any systemic changes it will make to ensure that the deficiencies will not recur—because RHS maintains there were no such deficiencies.

In light of the accelerated timeframe imposed by the Court—and given RHS's outright refusal to implement corrective actions with regard to such serious, extensive deficiencies as those highlighted above and those remaining in the SOD—the Department does not believe that any further progressive action regarding these deficiencies would be fruitful. Nor is such action required.

Under section 197.220 RSMo, the Department finds—based on the serious, extensive unresolved deficiencies cited in the SOD and the absence of an acceptable corrective-action plan from RHS with respect to those deficiencies—that there has been a substantial failure to comply with the requirements of sections 197.200 to 197.240 RSMo. The Department therefore denies RHS's application for a license renewal. This denial does not preclude RHS from resubmitting an application for license at any time, provided outstanding deficiencies are resolved.

Section 197.221 RSMo contains a right of review with the Administrative Hearing Commission for a license denial:

Any person aggrieved by an official action of the department of health and senior services affecting the licensed status of a person under the provisions of sections 197.200 to 197.240, including the refusal to grant, the grant, the revocation, the suspension, or the failure to renew a license, may seek a determination thereon by the administrative hearing commission pursuant to the provisions of section 621.045 and it shall not be a condition to such determination that the person aggrieved seek a reconsideration, a rehearing, or exhaust any other procedure within the department of health and senior services.

Sincerely,

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

January 4, 2019

Cathy Williams, SPHR, SHRM-SCP
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00151249***

Dear Cathy Williams:

The results of the recent complaint survey conducted at your facility on ***January 3, 2019*** indicate that your facility is in compliance with the State Licensure regulations for abortion centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-1588.

Respectfully,

Melinda Laughlin RN,BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosures

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 01/03/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments As directed by the Bureau of Ambulatory Care, an on-site, unannounced allegation survey was conducted on 01/03/19 for complaint #MO00151249. The allegation was found to be unsubstantiated with no deficiencies.	L 000		

Missouri Department of Health and Senior Services
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

February 27, 2019

Janice Thomas
Reproductive Health Services / Planned Parenthood
4251 Forest Park Avenue
Saint Louis, MO 63108

RE: ***Complaint Survey MO00152740***

Dear Janice Thomas:

The results of the recent complaint survey conducted at your facility on ***February 11, 2019*** indicate that your facility is in compliance with the State Licensure regulations for abortion centers in Missouri.

Please retain this material for your own records.

We welcome any questions at 573-751-1588.

Respectfully,

Melinda Laughlin RN,BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosures

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	C 02/11/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments As directed by the Bureau of Ambulatory Care, an on-site, unannounced allegation survey was conducted on 02/11/19 for complaint #MO00152740. The allegation was found to be unsubstantiated with no deficiencies.	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING _____ B. WING _____	06/03/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COLUMBIA CENTER, PLANNED PARENTHOOI	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments No deficiencies per Dean Linneman.	L 000		

Missouri Department of Health and Senior Services

TITLE (X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An unannounced on-site state licensure survey was conducted at this facility on 06/10/13 through 06/11/13. See below for findings. UPDATE 02/25/2014. This facility was found to be NOT performing abortion procedures. As they were not performing the procedure that required a license (and had no immediate plans to do so), a new license was not provided. Discussions were started between PP and DHSS regarding this process, with PP wishing to retain some semblance of the license, if for no other reason, so that if and when they ever reopened the facilty to perform abortions, the 2010 settlement agreement on the physical standards would still be in place. In general, DHSS was OK with this, and discussion about an additional amendment to the settlement agreement continued (we "close" the license with the agreement that a future provider [at the same location] would still have the relaxed construction standards in place from 2010. However, as of Feb 2014, there seems to have been no further movement toward an additional settlement agreement. A license has NOT been generated, nor will it be for the foreseeable future. An SOD for the June 2013 survey was never issued. This SOD and related survey processes have been held up since that time. After discussion with Section Administrator Dean Linneman, it was decided to officially close the file on both the facility and the 2013 survey of PP. (Pending a later reversal by OGC). --BAC Admin John Langston--02/25/14.	L 000		
L1106	19 CSR 30-30.060(1)(A)(3) Bylaws of the governing body shall Bylaws of the governing body shall require that an individual who complies with paragraph (1)(A)2.	L1106		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1106	Continued From page 1 of this rule shall be in charge in the absence of the administrator. This regulation is not met as evidenced by: Based on interview and policy review the facility failed to ensure that a policy was in place to designate the responsibilities and qualifications of an administrative designee when the administrator was absent from the facility. The facility did not conduct procedures at the time of the survey. Findings included: 1. During an interview on 06/11/13 at 10:30 AM Staff B, Director of Quality and Risk Management, stated that there is no policy which designated that a qualified person shall be in charge when the administrator is absent from the facility. 2. Review of the facility policy manual showed that no policy was in place to designate an individual to be in charge when the administrator was absent.	L1106		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on interview, and review of the Drug Enforcement Administration (DEA) and Bureau of Narcotics and Dangerous Drugs (BNDD) websites, the facility failed to maintain a DEA and a BNDD license. The facility did not conduct	L1111		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1111	Continued From page 2 procedures at the time of the survey. Findings included: 1. Review of the DEA website, http://www.deadiversion.usdoj.gov/drugreg/faq.htm#4 showed: - A separate registration is required for each principal place of business or professional practice where controlled substances are stored, administered, or dispensed by a person. 2. Review of the Missouri BNDD website, http://health.mo.gov/safety/bndd/faqs.php#1 showed: - Any person, business, or entity in Missouri that wants to conduct any activities with controlled substances must have a registration. - A separate registration is required at each separate location where controlled substances are stocked and stored. 3. During an interview on 06/10/13 at 2:00 PM, Staff C, Heath Center Manager, stated that patients were prescribed and/or administered Valium (a controlled substance > a drug or chemical whose manufacture, possession, or use is regulated by a government) prior to surgical abortions when the procedures had been conducted at the facility.	L1111		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1128	Continued From page 3 other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on interview, the facility failed to maintain an instruction manual from the manufacturer for the sterilizer used in the facility. The facility did not conduct procedures at the time of the survey. Findings included: During an interview on 06/11/13 at 3:00 PM, Staff G, Acting Administrator, Director of Health Center Operations, stated: - The facility did not have the original instruction manual for the sterilizer used at the facility, due to the age of the sterilizer; and - She had requested an instruction manual from the manufacturer following the surveyor's request to review the manual on 06/10/13.	L1128		
L1130	19 CSR 30-30.060(1)(B)(10) The facility shall have policies The facility shall have policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry. The facility may provide laundry services at the facility or utilize contract services. This regulation is not met as evidenced by: Based on interview and observation the facility	L1130		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1130	Continued From page 4 failed to ensure that clean linens were processed and stored separately from the processing of soiled linens. The facility did not conduct procedures at the time of the survey. Findings included: 1. Observation on 06/11/13 at 10:00 AM showed that in a room next to the laboratory were a clothes washer and dryer next to each other. On an open shelf in this room were an uncovered stack of approximately six patient gowns and three blankets. 2. During an interview on 06/11/13 at 10:00 AM Staff A, Licensed Practical Nurse, stated that he/she processed the laundry for the facility and the patient gowns were kept on the open shelf. The soiled linen was handled in this room before being placed in the clothes washer. Staff A stated that the facility did not have patients for abortion procedures but the processing and storage of the linen remained the same as when they had patients for these procedures.	L1130		
L1169	19 CSR 30-30.060(3)(I) An emergeny tray equipped to treat An emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest and cardiac arrest shall be immediately available to the procedure room and recovery room. This regulation is not met as evidenced by: Based on interview, the facility failed to maintain working batteries for the Automated External Defibrillator (AED) unit (a device that sends an electric shock to the heart that will restore the	L1169		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1169	Continued From page 5 natural heart rhythm to the victim during a cardiac arrest) that was to be kept on the facility crash cart. The facility did not conduct procedures at the time of the survey. Findings included: During an interview on 06/11/13 at 11:00 AM, Staff G, Acting Administrator, Director of Health Center Operations, stated that the AED unit needed replacement batteries and had recently ordered batteries.	L1169		
L1241	19 CSR 30-30.070(3)(A) Smoke detectors shall be located in all Smoke detectors shall be located in all rooms and in corridors at thirty-feet (30') intervals unless the building is rated Type II (222) fire-resistive or if it is a one (1)-story building rated Type II (111) protected-noncombustible as described in Standard on Types of Building Construction 1979 published by the NFPA. If the building is multistoried and rated combustible, it shall be protected throughout by an approved automatic sprinkler system; This regulation is not met as evidenced by: Based on observation and interview the facility failed to ensure that all smoke detectors required to be installed in the facility received routine testing to ensure proper operation annually. The facility did not conduct procedures at the time of the survey. Findings included: 1. Observation on 06/10/13 and 06/11/13 of the corridors and habitable areas of the facility	L1241		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1241	Continued From page 6 showed that a smoke detectors were present in all areas. 2. During an interview on 06/11/13 at 12:15 PM Staff C, manager, stated that he/she knew of no test or inspection that had ever been done for the smoke detectors to ensure that they functioned properly.	L1241		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 02/25/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments UPDATE 02/25/2014. This facility was found to be NOT performing abortion procedures. As they were not performing the procedure that required a license (and had no immediate plans to do so), a new license was not provided. Discussions were started between PP and DHSS regarding this process, with PP wishing to retain some semblance of the license, if for no other reason, so that if and when they ever reopened the facilty to perform abortions, the 2010 settlement agreement on the physical standards would still be in place. In general, DHSS was OK with this, and discussion about an additional amendment to the settlement agreement continued (we "close" the license with the agreement that a future provider [at the same location] would still have the relaxed construction standards in place from 2010. However, as of Feb 2014, there seems to have been no further movement toward an additional settlement agreement. A license has NOT been generated, nor will it be for the foreseeable future. An SOD for the June 2013 survey was never issued. This SOD and related survey processes have been held up since that time. After discussion with Section Administrator Dean Linneman, it was decided to officially close the file on both the facility and the 2013 survey of PP. (Pending a later reversal by OGC). --BAC Admin John Langston--02/25/14.	{L 000}		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 3, 2015

Vicki Casey (Vicki.Casey@ppkm.org)
Columbia Center, Planned Parenthood of Kansas and Mid-Missouri
711 N. Providence Rd
Columbia, MO 65203

Re: Initial Licensure Survey

Dear Ms. Casey:

An onsite initial licensure survey for your facility to provide abortion services began on 04/02/2015. The facility was found **not** to be in compliance with all regulatory requirements as described in 19 CSR 30-30.060 and 19 CSR 30-30.070. As a result, a license will **not** be issued until the following items have each been adequately addressed:

1. A check of all current employees to ensure that none appear on the Employee Disqualification List (EDL) maintained by the Department of Health and Senior Services as required for all facilities licensed under chapter 197 must be completed. Further, a method and policy to ensure that any new employee has this check done before hire and that the facility periodically checks the EDL for all employees must be in place.

2. Ensure that all physicians on the medical staff providing abortion services have received a complete credentialing packet to include: a)appointment and approval by the Governing Body; b)appropriate certificates for medications; c)approval of privileges; and d)a completed application to be on staff at the facility.

3. The facility will need appropriate certificates for medications via registration for Controlled Substances from the Bureau of Narcotics & Dangerous Drugs and the Drug Enforcement Agency (DEA).

4. The facility will need to submit a waiver/variance request for the provision of 19 CSR 30-30.070 (2)(N) which requires to be sized to accommodate at least four (4) recovery beds or recliners for each procedure room. Required space necessary is not available and facility staff indicated two (2) is sufficient for planned licensed services and workload.

5. The Facility initially plans to offer only medication-induced procedures, but to expand to surgical procedures later in the summer. As the equipment for surgical procedures has not been purchased and is not onsite, the facility is not currently prepared to provide the surgical services. BAC will need to revisit prior to permitting surgical procedures. Therefore, the license, when issued, will only approve the facility for medication-induced procedures. Please acknowledge in your written response your facility understands this limitation placed on your license.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	04/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments Findings letter issued 4/3/15 instead of SoD. See file for letter. Survey closed 7/15/15.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Missouri Department of Health and Senior Services
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

05/01/2015

RECEIVED MAY 07 2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: PRIDGEON, KIMBERLY DAWN
Registrant Number: 62779590

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 05/01/2015. The background screening, confirmation #116971850573, conducted on 05/01/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

The FCSR provides background screening information for employment purposes only. Any person who uses the information obtained from the registry for any purpose other than that specifically provided for in sections 210.900 to 210.936 is guilty of a class B misdemeanor, RSMo §210.921.3. The FCSR bases criminal history identification on the name, Social Security number and date of birth provided by the inquirer, not by the use of fingerprints. Please be advised that you must contact your licensing representative or other agency contact to determine whether this background screening meets state agency requirements for licensure, certification or registration. If you have questions or need assistance, you may contact the FCSR's toll free call center at 866-422-6872, or visit our Internet site at http://health.mo.gov/safety/fcsr/.

RECEIVED JUN - 1 2015

Planned Parenthood®
Care. No matter what.

Comprehensive Health of Planned Parenthood of Kansas and Mid-Missouri

CORPORATE BOARD RESOLUTION

Approval of Appointment of Medical Staff

I HEREBY CERTIFY that at a meeting of the Board of Directors of **Comprehensive Health of Planned Parenthood of Kansas and Mid-Missouri (CHPPKM)**, a corporation organized and existing under and by virtue of the laws of the State of Missouri, held on the 12th day of May, 2015, at which said meeting a quorum was present and acting throughout, the following resolution was adopted and ever since has been and now is in full force and effect.

RESOLVED, the Board of Directors approves the appointment of Dr. Colleen McNicholas as a contract abortion provider at the meeting of CHPPKM's Board of Directors held on May 12, 2015.

In witness whereof, I have hereunto set my hand this 12th day of May, 2015.

Marjorie Sable
Board Secretary

Americans United for Life

To ensure that every individual has the knowledge, opportunity and freedom to make informed private decisions about reproductive and sexual health.

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: WINDHAM, EMMA ANN
Registrant Number: 64955877

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562621, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

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Gail Vasterling
Director

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04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: MCNICHOLAS, COLLEEN
Registrant Number: 64495533

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/28/2015. The background screening, confirmation #116971561995, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: CASEY, VICKI LYNN
Registrant Number: 14258538

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562691, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: WARD, MARIA LUISA
Registrant Number: 64955830

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562747, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

The FCSR provides background screening information for employment purposes only. Any person who uses the information obtained from the registry for any purpose other than that specifically provided for in sections 210.900 to 210.936 is guilty of a class B misdemeanor, RSMo §210.921.3. The FCSR bases criminal history identification on the name, Social Security number and date of birth provided by the inquirer, not by the use of fingerprints. Please be advised that you must contact your licensing representative or other agency contact to determine whether this background screening meets state agency requirements for licensure, certification or registration. If you have questions or need assistance, you may contact the FCSR's toll free call center at 866-422-6872, or visit our Internet site at http://health.mo.gov/safety/fcsr/.

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
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04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: WILSON, KRISTIN L
Registrant Number: 64955883

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562832, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: OWENS, KORI LYNN
Registrant Number: 62380544

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562796, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

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P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	COMPREHENSIVE HEALTH OF PPKM (COMPREHENSIVE HEALTH OF PPKM)
BNDD Number:	2500027602
Description:	AMBULATORY SURGICAL CENTER
Street Address:	711 N PROVIDENCE RD
City/State/Zip:	COLUMBIA, MO 65203.4357
Phone Number:	573-875-4177
Registration Effective:	4/28/2015
Registration Expires:	4/30/2016
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	4/28/2015

Validation Date of the Registration is: 4/30/2015

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

COMPREHENSIVE HEALTH OF PPKM
711 N PROVIDENCE RD
COLUMBIA, MO 65203-0000-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC5215428	08-31-2018	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	HOSPITAL/CLINIC	05-11-2015

COMPREHENSIVE HEALTH OF PPKM
711 N PROVIDENCE RD
COLUMBIA, MO 65203-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (4/07)

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

APPLICATION FOR EMPLOYMENT

Colleen McNicholas DO

APPLICANT NAME

APPLICATION FOR EMPLOYMENT

Planned Parenthood of Kansas and Mid-Missouri is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, age, gender, sexual orientation, national origin, ancestry, disability, citizenship, genetic information, veteran service or status or any other characteristic protected under Federal or State law.

This application shall be considered active for a period not to exceed ***45 days***. Any applicant wishing to be considered for employment beyond this time period should complete another application at the end of that period.

Personal Information

Name (Last, First, Middle)	**E-Mail Address**	**Date of Application**
Click here to enter text. McNicholas, Colleen	mcnicholasc@wudosis.wush.edu	05/29/15

Have you ever worked under another name? If so, supply: Click here to enter text.	**Telephone Number with Area Code**
No	Click here to enter text. 314-747-6721

Current Address: Street	**City**	**State**	**Zip**	**Number of Years**
4533 Clayton Ave	St Louis	MO	63110	4

Past 7 Years Residency

Address: Street	**City**	**State**	**Zip**	**Number of Years**
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Address: Street Click here to enter text.	**City** Click here to enter text.	**State** Click here to enter text.	**Zip** Click here to enter text.	**Number of Years** Click here to enter text.
Address: Street Click here to enter text.	**City** Click here to enter text.	**State** Click here to enter text.	**Zip** Click here to enter text.	**Number of Years** Click here to enter text.
Address: Street Click here to enter text.	**City** Click here to enter text.	**State** Click here to enter text.	**Zip** Click here to enter text.	**Number of Years** Click here to enter text.

Are you available to work:	**Number of Hours:** Negotiable	**Date Available** 6/5/2015
☐**Full-Time** XPart-Time		

Position Applying for: ***(Check all that apply)*** ☐CMA ☐RN/LPN ☐Administrative ☐Health Center Manager
Other __Physician_____

Location: ☐ Overland Park ☐Wichita ☐North Kansas City XColumbia ☐Independence ☐ South Kansas City ☐Patty Brous
Other

Salary Requirements	**Days Available:** X Mon ☐ Tues X Wed ☐Thurs ☐ Fri ☐ Sat ☐ Sun	**Are you currently employed?** XYes ☐ No **If Yes, can we contact them?** XYes ☐ No
Click here to enter text. /Hour N/A Click here to enter text. /Year N/A		

How did you hear about Planned Parenthood of Kansas and Mid-Missouri or this position? Click here to enter text.

General Information

Have you been convicted of a felony within the last seven years? ☐ **Yes** X **No**
If yes, please describe: Click here to enter text.

Note: A conviction record is not an automatic bar to employment. A conviction will be considered only in relation to specific job requirements. An applicant shall be notified if an adverse decision was based on conviction data.

Training and Skills

List special Skills, Proficiencies or experiences which you feel may especially qualify you for the position for which you are applying: Click here to enter text.

EDUCATION AND HISTORY

Name	Location and Telephone	Course	Years Completed Degree
High School/GED Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Undergraduate Benedictine University	Lisle ILL	Forensic Chemistry	Bachelor of Science
Graduate Kirksville College of Osteopathic Medicine	Kirksville MO	Osteopathic Medicine	Doctor of Osteopathy
Post Graduate Atlanta Medical Centers Washington University	Atlanta GA ST Louis MO	Internship Residency	

WORK EXPERIENCE – STARTING WITH MOST RECENT

Name of Employer Washington University	**4533 Clayton Avenue** **St Louis MO 63110**	**Date Employed** **From:** 2009 **To:** Current
Telephone of Employer 314-747-6721	**Supervisor's Name and Title** Click here to enter text. Jeffery Peipert	**Rate of Pay:** N/A
Position or Title Doctor of Osteopathy	**Reason for Leaving** N/A	
Description of Duties:		

NEXT PREVIOUS EMPLOYER

Name of Employer DuPage County Coroner's Office	**Address of Employer** **Carol Stream IL**	**Date Employed** **From:** 1999 **To:** 2003
Telephone of Employer Click here to enter text.	**Supervisor's Name and Title** Click here to enter text.	**Rate of Pay:** Click here to enter text.
Position or Title Pathology Assistant	**Reason for Leaving** Graduate School	
Description of Duties: Assisted with autopsy, organ harvesting and toxicology samples		

NEXT PREVIOUS EMPLOYER

Name of Employer Benedictine University	**Address of Employer** **Lisle, IL**	**Date Employed** **From:** 2002 **To:** 2002
Telephone of Employer Click here to enter text.	**Supervisor's Name and Title** Click here to enter text.	**Rate of Pay:** Click here to enter text.
Position or Title Cell Biology Researcher	**Reason for Leaving** Graduate School	
Description of Duties: Lab animal care, tissue culture, preparation and maintenance of cell lines, media preparation		

WORK RELATED REFERENCES
(Provide at least 3)
Please note that family and friends are not considered relevant employment references.

Name of Contact PPSLR – Mary Kogut	**Period Known** **From:** 2012 **To:** Current
Contact Telephone Number 314-531-7526	**Mailing Address** 4251 Forest Park Ave St Louis MO 63108
Contact Email Address	
How did you know this individual: Currently Employed	

WORK RELATED REFERENCES

Name of Contact Click here to enter text. Tessa Madden	**Period Known** **From:** 2011 **To:** Current
Contact Telephone Number 314-747-6721	**Mailing Address** 4533 Clayton Ave St Louis MO 63110
Contact Email Address Click here to enter text. maddent@wustl.edu	
How did you know this individual: Click here to enter text. college	

WORK RELATED REFERENCES

Name of Contact Click here to enter text. David Eisenberg	**Period Known** **From:** Click here to enter a date. 2011 **To:** Click here to enter a date. Current
Contact Telephone Number Click here to enter text. 314-747-1331	**Mailing Address** Click here to enter text.
Contact Email Address Click here to enter text. eisenbergd@wustl.edu	
How did you know this individual: Click here to enter text. Colleague	

Work Related Reference

Name of Contact Click here to enter text.	**Period Known** **From:** Click here to enter a date. **To:** Click here to enter a date.
Contact Telephone Number Click here to enter text.	**Mailing Address** Click here to enter text.
Contact Email Address Click here to enter text.	
How did you know this individual: Click here to enter text.	

Americans United for Life

READ CAREFULLY BEFORE SIGNING BELOW
(Signature required in order to be considered for employment.)

1. I understand that Planned Parenthood of Kansas and Mid-Missouri will consider any requests for accommodations of physical or mental disabilities by an otherwise qualified person at any time before or after employment begins. I understand that the company would appreciate as much advance notice as possible regarding request for accommodation, and that documentation of the need for accommodation might be required.

2. I understand that I may be required to pass a drug screen. Successful completion of this test is a condition of employment. I further understand that I, as all Planned Parenthood of Kansas and Mid-Missouri employees, am subject to ongoing drug testing program and will be required to pass such tests as a condition of continued employment.

3. I understand that a background investigation including my employment and criminal history will be performed as a condition of employment; I hereby authorize Planned Parenthood of Kansas and Mid-Missouri and or its agents to thoroughly request, receive and verify all statements and information contained in my application or resume and as relevant to this background investigation. I release Planned Parenthood of Kansas and Mid-Missouri from all liability for any damages that may result from doing so. I authorize any persons or organizations referenced in this application, including but not limited to employers, educational institutions, licensing agencies, law enforcement agencies, financial institutions, government agencies, courts, and other persons or organizations to give you any and all information concerning my previous employment, education, or any other information they might have, personal or otherwise, with regard to any of the subjects covered by this application. I release all such parties from all liability for any damages that may result from furnishing such information to Planned Parenthood of Kansas and Mid-Missouri.

4. I understand that employment is contingent upon my complying with the employment verification requirements of the Immigration Reform and Control Act.

5. I certify that I personally completed this application and that the information provided in this application (and accompanying resume, if any) is true and complete. I understand that any misstatement, falsification, omission or misrepresentation on this application or in any interview is grounds for refusal to hire, or if I am hired and the same is discovered thereafter, I will be separated. I understand that all information provided by me on this application or in any interview is subject to verification.

6. I acknowledge that if I am employed by the company, my employment will be at-will, that I will be required to follow all rules and regulations of the company and that my employment may be terminated with or without cause, with or without notice, at the option of myself or the company. No one other than the President has the authority to enter into any agreement for employment for any specified period of time or to make any agreement contrary to the foregoing, either before commencement of employment or after I have become employed.

7. I certify that I have read or have had read to me, items 1, 2, 3, 4, 5 and 6 above. I understand the contents and hereby acknowledge receipt and understanding of this information. Further, I confirm that I desire to be considered for employment under these conditions.

Click here to enter text.

Signature of Applicant

5/29/2015

Date

Americans United for Life

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

CONSUMER DISCLOSURE AND AUTHORIZATION FORM

Disclosure Regarding Background Investigation

Planned Parenthood of Kansas and Mid-Missouri (the "Company") may request, for lawful employment purposes, background information about you from a consumer reporting agency in connection with your employment or application for employment (including independent contractor assignments, as applicable). This background information may be obtained in the form of consumer reports and/or investigative consumer reports (commonly known as "background reports"). An "investigative consumer report" is a background report that includes information from personal interviews (except in California, where that term includes background reports with or without information obtained from personal interviews), the most common form of which is checking personal or professional references. These background reports may be obtained at any time after receipt of your authorization and, if you are hired or engaged by the Company, throughout your employment or your contract period, as allowed by law.

HireRight, Inc. ("HireRight"), or another consumer reporting agency, will prepare or assemble the background reports for the Company. HireRight is located and can be contacted by mail at 5151 California, Irvine, CA 92617, and HireRight can be contacted by phone at (800) 400-2761. Information about HireRight's privacy practices is available at www.hireright.com/Privacy-Policy.aspx.

The background report may contain information concerning your character, general reputation, personal characteristics, mode of living, and credit standing. The types of information that may be obtained include, but are not limited to: social security number verifications; address history; credit reports and history; criminal records and history; public court records; driving records; accident history; worker's compensation claims; bankruptcy filings; educational history verifications (e.g., dates of attendance, degrees obtained); employment history verifications (e.g., dates of employment, salary information, reasons for termination, etc.); personal and professional references checks; professional licensing and certification checks; drug/alcohol testing results, and drug/alcohol history in violation of law and/or company policy; and other information bearing on your character, general reputation, personal characteristics, mode of living and credit standing.

This information may be obtained from private and public record sources, including, as appropriate: government agencies and courthouses; educational institutions; former employers; and, for investigative consumer rep01ts, personal interviews with sources such as neighbors, friends, former employers and associates; and other information sources. If the Company should obtain information bearing on your credit worthiness, credit standing or credit capacity for reasons other than as required by law, then the Company will use such credit information to evaluate whether you would present an unacceptable risk of theft or other dishonest behavior in the job for which you are being evaluated.

You may request more information about the nature and scope of an investigative consumer report, if any, by contacting the Company.

A summary of your rights under the Fair Credit Reporting Act, as well as certain state-specific notices, are also being provided to you.

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

AUTHORIZATION of BACKGROUND INVESTIGATION

I have carefully read and understand this Disclosure and Authorization form and the attached summary of rights under the Fair Credit Reporting Act. By my signature below, I consent to preparation of background reports by a consumer rep01ting agency such as HireRight, Inc. ("HireRight"), and to the release of such background reports to the Company and its designated representatives and agents, for the purpose of assisting the Company in making a determination as to my eligibility for employment (including independent contractor assignments, as applicable), promotion, retention or for other lawful employment purposes. I understand that if the Company hires me or contracts for my services, my consent will apply, and the Company may, as allowed by law, obtain additional background reports pertaining to me, without asking for my authorization again, throughout my employment or contract period from HireRight and/or other consumer reporting agencies.

I understand that information contained in my employment or contractor application, or otherwise disclosed by me before or during my employment or contract assignment, if any, may be used for the purpose of obtaining and evaluating background reports on me. I also understand that nothing herein shall be construed as an offer of employment or contract for services.

I hereby authorize all of the following, without limitation, to disclose information about me to the consumer reporting agency and its agents: law enforcement and all other federal, state and local agencies, learning institutions (including public and private schools, colleges and universities), testing agencies, information service bureaus, credit bureaus, record/data repositories, courts (federal, state and local), motor vehicle records agencies, my past or present employers, the military, and all other individuals and sources with any information about or concerning me. The information that can be disclosed to the consumer reporting agency and its agents includes, but is not limited to, information concerning my employment and earnings history, education, credit history, motor vehicle history, criminal history, military service, professional credentials and licenses.

By my signature below, I also certify the information I provided on and in connection with this form is true, accurate and complete. I agree that this form in original, faxed, photocopied or electronic (including electronically signed) form; will be valid for any background reports that may be requested by or on behalf of the Company.

Applicant Name: **Last** Click here to enter text. **First** Click here to enter text. **Middle** Click here to enter text.

Applicant Signature

5/29/2015
Date

Americans United for Life

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

Para informacion en espaiiol, visite www.consumerfinance.gov/leammore o escribe a Ia ConsumerFinancial Protection Bureau, 1700 G Street N.W., Washington DC 20552.

A SUMMARY OF YOUR RIGHTS UNDER THE FAIR CREDIT REPORTINGACT

The federal Fair Credit Reporting Act (FCRA) promotes the accuracy, fairness, and privacy of information in the files of consumer reporting agencies. There are many types of consumer rep01ting agencies, including credit bureaus and specialty agencies (such as agencies that sell inf01mation about check writing histories, medical records, and rental history records). Here is a summary of your major rights under the FCRA. For more information, including information about additional rights, go to www.consumerfinance.gov/learnmore or write to: Consumer Financial Protection Bureau, 1700 G Street N.W., Washington, DC 20552.

- You must be told if information in your file has been used against you. Anyone who uses a credit report or another type of consumer report to deny your application for credit, insurance, or employment - or to take another adverse action against you - must tell you, and must give you the name, address, and phone number of the agency that provided the information.
- You have the right to know what is in your file. You may request and obtain all the information about you in the files of a consumer reporting agency (your "file disclosure"). You will be required to provide proper identification, which may include your Social Security number. In many cases, the disclosure will be free. You are entitled to a free file disclosure if:
    - a person has taken adverse action against you because of information in your credit report;
    - you are the victim of identity theft and place a fraud alert in your file;
    - your file contains inaccurate information as a result of fraud;
    - you are on public assistance;
    - you are unemployed but expect to apply for employment within 60 days.
- In addition, all consumers are entitled to one free disclosure every 12 months upon request from each nationwide credit bureau and from nationwide specialty consumer rep01ting agencies. See www.consumerfinance.gov/learn more for additional information.
- You have the right to ask for a credit score. Credit scores are numerical summaries of your creditworthiness based on information from credit bureaus. You may request a credit score from consumer reporting agencies that create scores or distribute scores used in residential real property loans, but you will have to pay for it. In some mortgage transactions, you will receive credit score information for free from the mortgage lender.
- You have the right to dispute incomplete or inaccurate information. If you identify information in your file that is incomplete or inaccurate, and report it to the consumer reporting agency, the agency must investigate unless your dispute is frivolous. See www.consumerfinance.gov/learnmore for an explanation of dispute procedures.
- Consumer reporting agencies must correct or delete inaccurate, incomplete, or unverifiable information. Inaccurate, incomplete or unverifiable information must be removed or corrected, usually within 30 days. However, a consumer reporting agency may continue to report information it has verified as accurate.
- Consumer reporting agencies may not report outdated negative information. In most cases, a consumer reporting agency may not report negative information that is more than seven years old, or bankruptcies that are more than 10 years old.
- Access to your file is limited. A consumer reporting agency may provide information about you only to people with a valid need-- usually to consider an application with a creditor, insurer, employer, landlord, or other business. The FCRA specifies those with a valid need for access.
- You must give your consent for reports to be provided to employers. A consumer reporting agency may not give out information about you to your employer, or a potential employer, without your written consent given to the employer. Written consent generally is not required in the trucking industry. For more information, go to www.consumerfinance.gov/learnmore.
- You may limit "prescreened" offers of credit and insurance you get based on information in your credit report. Unsolicited "prescreened" offers for credit and insurance must include a toll-free phone number you can call if you choose to remove your name and address from the lists these offers are based on. You may opt-out with the nationwide credit bureaus at 1-888-567-8688.

- You may seek damages from violators. If a consumer reporting agency, or, in some cases, a user of consumer reporter or a furnisher of information to a consumer reporting agency violates the FCRA, you may be able to sue in state or federal court.
- Identity theft victims and active duty military personnel have additional rights. For more information, visit www.consumerfinance.gov/learnmore .

States may enforce the FCRA, and many states have their own consumer reporting laws. In some cases, you may have more rights under state law. For more information, contact your state or local consumer protection agency or your state Attorney General. For Information about your Federal rights contact:

QUESTIONS OR CONCERNS

States may enforce the FCRA, and many states have their own consumer reporting laws. In some cases, you may have more rights under state law. For more information, contact your state or local consumer protection agency or your state Attorney General. For information about your federal rights, contact:

TYPE OF BUSINESS:	CONTACT:
1. a. Banks, savings associations, and credit unions with total assets of over $10 billion and their affiliates. b. Such affiliates that are not banks, savings associations, or credit unions also should list, in addition to the Bureau:	a. Bureau of Consumer Financial Protection 1700 G Street NW Washington, DC 20006 b. Federal Trade Commission: Consumer Response Center – FCRA Washington, DC 20580 (877) 382-4357
2. To the extent not included in item 1 above: a. National banks, federal savings associations, and federal branches and federal agencies of foreign banks b. State member banks, branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act c. Nonmember Insured Banks, Insured State Branches of Foreign Banks, and insured state savings associations d. Federal Credit Unions	a. Office of the Comptroller of the Currency Customer Assistance Group 1301 McKinney Street, Suite 3450 Houston, TX 77010-9050 b. Federal Reserve Consumer Help Center P.O. Box 1200 Minneapolis, MN 55480 c. FDIC Consumer Response Center 1100 Walnut Street, Box #11 Kansas City, MO 64106 d. National Credit Union Administration Office of Consumer Protection (OCP) Division of Consumer Compliance & Outreach DCCO) Alexandria, VA 22314
3. Air carriers	Asst. General Counsel for Aviation Enforcement & Proceedings Department of Transportation 400 Seventh Street SW, Washington, DC 20590
4. Creditors Subject to Surface Transportation Board	Office of Proceedings, Surface Transportation Board Department of Transportation 1925 K Street NW, Washington, DC 20423
5. Creditors Subject to Packers and Stockyards Act	Nearest Packers and Stockyards Administration area supervisor
6. Small Business Investment Companies	Associate Deputy Administrator for Capital Access United States Small Business Administration 406 Third Street, SW, 8th Floor, Washington, DC 20416
7. Brokers and Dealers	Securities and Exchange Commission 100 F St NE, Washington, DC 20549
8. Federal Land Banks, Federal Land Bank Associations, Federal Intermediate Credit Banks, and Production Credit Associations	Farm Credit Administration 1501 Farm Credit Drive, McLean, VA 22102-5090
9. Retailers, Finance Companies, and All Other Creditors Not Listed Above	FTC Regional Office for region in which the creditor operates or Federal Trade Commission: Consumer Response Center – FCRA Washington, DC 20580 (877) 382-4357

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

CONSENT AND RELEASE FOR SUBSTANCE TESTING

I understand that the purpose of the Substance Abuse policy is to provide a safe working environment. Accordingly, I understand that as a condition of employment with Planned Parenthood of Kansas and Mid-Missouri, I will be required to undergo substance testing. I also understand that a positive drug/alcohol test may exclude me from employment. I further understand that I am also subject to ongoing testing requirement under the company policy. In addition, I understand that a positive substance test at any time during my employment with Planned Parenthood of Kansas and Mid-Missouri may be cause for dismissal.

I hereby consent to substance testing as required by Planned Parenthood of Kansas and Mid-Missouri. I further authorize the release of all information and records, including test results of the screening or testing to Planned Parenthood of Kansas and Mid-Missouri.

I hereby release Planned Parenthood of Kansas and Mid-Missouri from any and all claims arising from the administration of such tests.

I have read and understand this consent and release form, and have signed it voluntarily.

Print Name: Click here to enter text.

Signature:

Date: 5/29/2015

Americans United for Life

CURRICULUM VITAE
Colleen Patricia McNicholas, D.O.

Date: February 2011

Personal Information:

Sex:	Female
Date of Birth:	December 10, 1980
Place of Birth:	Chicago, IL

Citizenship: United States of America

Address and Telephone Numbers:

Hospital:
Department of Obstetrics and Gynecology
Washington University in St. Louis
Campus Box 8064
4911 Barnes-Jewish Hospital Plaza
Saint Louis, Missouri 63110-1094

Home:
3339 Wisconsin Ave
Saint Louis, Missouri 63118

Present Position:
Resident, Department of Obstetrics and Gynecology
Washington University in Saint Louis
Barnes-Jewish Hospital

Education:

Undergraduate:	1998-2003	Benedictine University Lisle, Illinois B.S. Forensic Chemistry
Graduate:	2003-2007	Kirksville College of Osteopathic Medicine Kirksville, MO Doctor of Osteopathy
Postgraduate:	2007-2008	Atlanta Medical Centers Atlanta, Georgia Internship
	2008-current	Washington University in Saint Louis Residency

Employment:

1999-2003	***Pathology Assistant,*** Dupage County Coroner's Office, Carol Stream IL Assisted with autopsy, organ harvesting, and toxicology samples
2000-2002	***Cell Biology Researcher,*** Benedictine University, Lisle IL Lab animal care, tissue culture, preparation and maintenance of cell lines, media preparation, autoclave sterilization
2000-2002	***Student LabTech (Chemistry),*** Benedictine University, Lisle IL

Maintenance of chromatography equipment, stock solutions, and general lab care.

2009-current **Washington University School of Medicine gynecology clinical teaching**
Clinical instruction on pelvic and breast exam skills

Medical Licensure:

2007-current Missouri Temporary Medical License
#2008015965

Honors and Awards:

2006 *Presidents Award*: Women in Medicine
2003 *Senior Academic Award: College of Arts and Science*, Benedictine University
2002 *PGG Industries Foundation J Earl Burrell Scholarship*, Benedictine University
2001 *Gregory Snoke Memorial Scholarship*, Benedictine University
2001 *American Chemical Society Analytical Achievement Award*, Benedictine University
2001 *American Chemical Society Division of Analytical Chemistry 2001 Undergraduate Award*, Benedictine University

Editorial Responsibilities:

2009-current Reviewer, American Journal of Obstetrics and Gynecology

Professional Societies and Organizations:

2010-current ***Member***, Missouri Association of Osteopathic Physicians
2008-current ***Board Member***, St Louis Obstetrics and Gynecology Society
2007-current ***Member***, American Medical Association
2006-current ***Member***, Association of Reproductive Health Professionals
2006-current ***Member***, American College of Obstetrics and Gynecology
2006-current ***Member***, Gay and Lesbian Medical Association
2003-current ***Member***, Medical Students for Choice
2003-current ***Member***, American Osteopathic Association

Invited Presentations:

Sept 2010 Oral Presentation, Association of Reproductive Healthcare providers
Madden T, McNicholas CP, Secura GM, Allsworth JE, Zhao Q, Peipert JF. Rates of Expulsion and Continuation of Intrauterine Contraception at 12 months in Nulliparous and Adolescent Women

April 2010 Oral Presentation, Rothman Resident Research Day
McNicholas CP, Madden T, Secura GM, Allsworth JE, Zhao Q, Peipert JF. Rates of Expulsion and Continuation of Intrauterine Contraception at 12 months in Nulliparous and Adolescent Women

MCNICHOLAS, COLLEEN
REPRODUCTIVE HEALTH SERVICES OF PLANNED
4251 FOREST PARK AVE.
ST LOUIS, MO 63108-2810-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BM2743789	01-31-2017	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	PRACTITIONER	12-17-2013

MCNICHOLAS, COLLEEN
REPRODUCTIVE HEALTH SERVICES OF PLANNED
4251 FOREST PARK AVE.
ST LOUIS, MO 63108-2810

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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BM2743789	01-31-2017	$731

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2,2N, 3,3N,4,5,	PRACTITIONER	12-17-2013

MCNICHOLAS, COLLEEN
REPRODUCTIVE HEALTH SERVICES OF PLANNED
4251 FOREST PARK AVE.
ST LOUIS, MO 63108-2810

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Form DEA-223 (4/97)

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	MCNICHOLAS, COLLEEN P
BNDD Number:	53597417
Description:	MEDICAL DOCTOR
Street Address:	4251 FOREST PARK AVE
City/State/Zip:	ST LOUIS, MO 63108.2810
Phone Number:	314-531-7526
Registration Effective:	7/15/2014
Registration Expires:	7/31/2015
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	7/15/2014

Validation Date of the Registration is: 2/23/2015

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

Planned Parenthood®
of Kansas and Mid-Missouri

Clinical Privileges to Perform Ultrasound

Name of person requesting privileges: Colleen McNicholas

Previous experience or certifications in Ultrasound Services: >3yrs @ PPSLR

Trainee initials below:

CM 1. I have successfully completed the CAPS Ultrasound CD training and/or passed the test. Date completed: 4/1/15

_____ 2. During proctoring, I performed approximately _____ (number) sonograms (if applicable).

_____ 3. I am familiar with how to change the image characteristics on an ultrasound machine and basic troubleshooting techniques (enlarging, changing contrast).

_____ 4. I am able to perform the items checked below.

- ☑ Identify the uterus in pregnant and non-pregnant women
- ☑ Obtain images of uterus in early pregnancy in longitudinal and transverse planes
- ☑ Identify an intrauterine pregnancy
- ☑ Identify embryonic (fetal) pole and measure CRL (know formula 42 plus largest CRL)
- ☑ Identify gestational sac and measure mean sac size (know formula 30 plus mean gestational sac)
- ☑ Identify characteristics of normal and abnormal gestational sac
- ☑ Identify yolk sac
- ☑ Identify cardiac activity
- ☑ Identify multiple gestations (if seen during training)
- ☑ Identify normal sonographic findings following abortion (thickness of endometrial stripe)
- ☑ Identify BPD and measures BPD correctly
- ☑ Assure that patients are informed of their option to view the ultrasound image and of their option to be informed if there is a multiple pregnancy
- ☑ Able to document findings consistently and complete the ultrasound form correctly
- ☑ Recognize when findings require evaluation by physician

If applicable:

- ☑ Proficiency in performing ultrasound to identify intrauterine IUC
  - ☑ Paragard IUC ☑ Mirena IUC
- ☑ Proficiency in interpreting location (intrauterine placement) of IUC
  - ☑ Paragard IUC ☑ Mirena IUC

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For 2nd trimester privileging:
- [x] Femur length
- [x] Placental localization

Other Essential Proficiencies:
- [x] Provides appropriate patient information regarding procedure, its purpose and limitations
- [x] Queries/acknowledges patient's feelings around abortion decision and the ultrasound imaging procedure
- [x] Properly cleans, maintains equipment and disposes of contaminated supplies

[signature] 4/1/15
Signature of Trainee Date

The following staff person, _____, has been observed by the Program Director of Ultrasound Services or their designee, has proven proficiency in the above activities, and is granted privileges as below:

- [ ] First-trimester ultrasound targeted for medication or surgical abortion services
  - [ ] Performance of ultrasound
  - [ ] Interpretation of ultrasound
- [ ] Second trimester ultrasound targeted for surgical abortion services
  - [ ] Performance of ultrasound
  - [ ] Interpretation of ultrasound
- [ ] Localization of IUC
  - [ ] Performance of ultrasound (licensed health professional, certified sonographer only
  - [ ] Interpretation of ultrasound (clinician only – APC or physician)

[signature] ~~4/01/15~~ 04/01/15
Signature, Ultrasound Program Director or designee Date

Title

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Training and Onboarding Requirements Checklist for Contract Physicians

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Mandatory Reporting Roles and Responsibilities and Services to Minors Compliance (Parental Involvement/Consent)	HR 1. b & d, RC 3. a & b, MIN 1. d	Anyone in the following categories who has contact with clients or minors: full-time employees, part-time employees, per diem employees, independent contractors, volunteers, students and trainees. Exception: "hands-off" students/trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Managing Suspicious Encounters	HR 1. b & d LSS 3. b	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees. Exception: "hands-off" students/trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Ultrasound in Abortion Care	HR 3. k HR 4. l RQM 4 e	Anyone in the following categories who provides ultrasound services: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees. Exception: "hands-off" students/trainees.	[redacted]	~~Yet to be Completed~~ 4/1/15

Talking About Abortion	HR 3. j HR 4. h	Anyone in the following categories who talks to women about pregnancy options (including those who work in health centers that do not provide abortion on site): full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students, and trainees. Exception: "hands-off" students/trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Orientation to the Abortion Pill	HR 3. m HR 4. j	Anyone in the following categories who talks to clients about abortion (including those who do not provide abortion services) is required to complete modules one and two of this CAL course: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees. Module three is only required for licensed clinical staff (employees, volunteers, independent contractors, students and trainees) who assess for expected effects, side effects, complications, and completion of the procedure.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Affiliate-Wide Risk and Quality Management (RQM) Program	RQM 2. a HR 1. d	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	Update on PPKM Specific Policy 4/15/15 11/14/14
Fraud Risk Management	RQM 3. f	Full-time employees, part-time employees, and per diem employees, volunteers, and independent contractors.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Safety and Security Training	LSS 2. c	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	met with Director of Security PPKM 3/13/15

Medical Record Policies and Documentation	MR 1 MR 2	Anyone in the following categories who works in health centers and/or has contact with medical records: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Medical Standards and Guidelines Protocol Changes	CS 3. b	Anyone in the following categories who works in health centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	Reviewed access to MS&G @ PPKM 4/15/15 11/14/14
Intimate Partner Violence (IPV) and Reproductive Coercion	RC 3	Anyone in the following categories who works in health centers or education programs: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Productivity Goals and Practices	FH-BO 2.	Anyone in the following categories who works in the health centers and call centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☒ Training does not apply to this contracted physician ☐ Training was completed elsewhere (specify where)	
HIPAA Privacy and Security	RC 4. c RC 5. c	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	Met with Director of Security of PPICM 3/18/15
Customer Service Practices and Goals	FH-BO 4.	Anyone in the following categories who works in the health centers and call centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☒ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14

-OSHA Regulations	MPP 5. RC 1. a	Anyone in the following categories who works in the health centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
CLIA Regulations	MPP 6.	Anyone in the following categories who works in the health centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Clinical Staff Orientation	OTE 3.	Anyone in the following categories who works in the health centers and call centers: full-time employees, part-time employees, per diem employees, independent contractors.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Pharmaceuticals (Preparation and Provision of Medications)	CS 4	Anyone in the following categories involved in the preparation and provision of medications: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Board Governance & Fiduciary Responsibilities	BD 3. b	All volunteers who serve on the affiliate board of directors and/or the budget and finance committee.	Choose one: ☐ Training was completed at affiliate ☒ Training does not apply to this contracted physician ☐ Training was completed elsewhere (specify where)	
Human Resources Training on Diversity and Cultural Competency in the Workplace	HR 2. c	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14

501(c)(3) and 501(c)(4) Non-Profit Organization Allowable Guidelines	PA 1. e	Anyone in the following categories who is involved with public affairs, development and finance: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PHSU	11/19/14
Safety and Security Drills	LSS 2. m	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	☒ Site-specific briefing given by affiliate	4/15/15
Fire Drills	LSS 2. k	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	☒ Site-specific briefing given by affiliate	4/15/15
Medical Emergency Drills	MMP 4. f OTE 3. f	Anyone in the following categories who works in health centers: full-time employees, part-time employees, per diem employees, independent contractors.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☐ Training was completed elsewhere(specify where)	4/15/15

We confirm that Colleen McNicholas *an independent contractor, has completed all required trainings that pertain to his/her contracted function(s).*

Contracted Physician — Date 4/28/15

Human Resources — Date

Medical Director — Date 04/04/2015

This checklist should be in the contract provider's personnel file. During an accreditation review, all contract physician files will be included in the personnel file audit.

CLINICIAN SKILLS CHECKLIST: PROCTORING FORM

Name/Title: Colleen McNicholas Date of Hire: _____

*The proctor should date and initial each category observed.

Area of Competence	Demonstrates Competence	Needs Supervision	Desires Training	Not trained or observed
Medical Records				
Interviewing/Hx taking				
Charting				
Informed Consent				
Client Education				
Referral/Follow-up system				
Productivity goals				
Lab Microscopy				
Venipuncture				
Wet Mounts/KOH/pH				
Dipstick				
Hematocrit				
Obtaining STD tests				
Exposure control procedures				
Other				
Procedures/Treatments # of procedures observed				
Vital signs				
IUC insertion (CU IUD/LNG IUS)	X			
Implanon insertion	X			
Implant removal				
Endometrial biopsy				
Ultrasound				
TCA/BCA application				
Vulvar Biopsy				
IM injection				
Diaphragm fitting				
FemCap fitting				
Emergency plans/drugs				
Skin Biopsy				
MVA	X			
Other				

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Area of Competence	Demonstrates Competence	Needs Supervision	Desires Training	Not trained or observed
Education				
Hormonal Contraceptives -General -Initiation -Problem Management				
Emergency contraception				
IUC	X			
Barrier Contraceptives				
Spermicide and Condoms				
Reproductive Life Planning				
Pregnancy Options				
Abortion -Medication -Surgical	X			
Other				
STDs/Vaginitis/UTI				
Bacterial Vaginosis				
Bartholinitis				
Candidiasis				
Cervicitis				
Chlamydia				
Gonorrhea				
HSV				
HIV counseling				
HPV				
Molluscum				
Pediculosis				
Syphilis				
Trichomonas				
UTI				
Other				
GYN Conditions				
Abnormal cytology/HPV follow up				
Abnormal Bleeding				
Amenorrhea				
Dysmenorrhea				
PID				
Galactorrhea				
Abnormal breast conditions				
Infertility				
Gestational Sizing				
HT/ET				
Other				

CLINICAL PRIVILEGING FORM

Colleen McNicholas has been granted clinical privileges for the following:

Date	Service	Signature of Medical Director or physician designee
4/15/15	☒ 1st trimester Surgical Abortion	
4/15/15	☒ Abortion pill	
4/15/15	☒ 2nd trimester Surgical abortion	
4/15/15	☒ Conscious Sedation	
	☐ Transabdominal Tubal Sterilization	
	☐ Hysteroscopic Tubal Sterilization	
	☐ Vasectomy	
	☐ Hysteroscopy	
	☐ LEEP	
	☐ Cryotherapy	
	☐ Colposcopy	
	☐ Endometrial Biopsy	
	☐ Vulvar Biopsy	
	☐ Fine Needle Aspiration	
	☐ Simple Cyst Aspiration	
4/15/15	☒ IUC insertion	
4/15/15	☒ Implanon insertion	
	☐ Implant removal	
4/15/15	☒ Standard U/S (Abortion)	
4/15/15	☒ Limited U/S (Abortion)	
	☐ Standard U/S (Pregnancy)	
4/15/15	☐ Limited U/S (Pregnancy)	
	☒ Limited U/S for IUC localization	
	☐ Standard U/S (GYN)	
	☐	
	☐	
	☐	

List any formal training clinician received for service(s) noted above:

Service	Year	Length of Training	Didactic component	Clinical Component
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no

I have read and understand the KM protocol. I agree to practice in accordance with this protocol when I am caring for clients at PPACM.

Clinician _____ Date 4/24/15

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Area of Competence	Demonstrates Competence	Needs Supervision	Desires Training	Not trained or observed
Cervical Screening				
Obtaining a Pap/HPV test				
Colposcopy				
Cryotherapy				
LEEP				
Abortion Services				
Surgical Abortion	X			
Medication Abortion	X			
Post-abortion check-up	X			
Recovery Room	X			
Management of complications	X			
High Alert Follow-up	X			
POC evaluation	X			
Other				
Referral Follow-up				

Proctor Signature: K Milburn Date: 4/24/15

RECOMMENDATION:

☒ Approved to provide services as checked in Column I above.

☐ Needs supervised clinical practice in the following areas:

Collum is currently practicing AB Services within an accredited affiliate

Plan for providing supervised clinical practice:

☐ Needs additional training in:

Plan for providing additional training (Journal review, In-service training, On-line training, CEU/Conference)

Signature of Clinician: [signature] Date: 4/24/15

Signature of MD or Physician Designee: [signature] Date: 5/04/2015

Print

Item Name	Status	Marked Complete By
Ultrasound in Abortion Care Advanced Placement (AP) Exam- Advanced **This advanced skills exam may be taken and passed to place out of courses 10-14 for Ultrasound in Abortion Care. Please note: In order to receive CME/ CE credit for the Ultrasound in Abortion Care Staff Training series, all 14 courses must be successfully completed.** Registration Date:04/01/2015	**Successful** On:04/01/2015 Score:85	
Ultrasound in Abortion Care Advanced Placement (AP) Exam- Basic **This basic skills exam may be taken and passed to place out of courses 1-9 of the Ultrasound in Abortion Care Series. Please note: In order to receive CME/ CE credit for the Ultrasound in Abortion Care Staff Training series, all 14 courses must be successfully completed.** Registration Date:03/31/2015	**Successful** On:04/01/2015 Score:95	

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PHYSICIAN PERFORMANCE REVIEW SUMMARY

Name of Physician: _____

The following section to be completed by the Vice President of Patient Services
Administrative Review

Based on professional communication, collaborative patient management, and/or individual patient care, the above physician performed satisfactorily in the following areas:

1.	Customer Orientation — understands, commits to and practices a market and customer oriented approach to heal care delivery. Treats clients with respect and non-judgmentally. Clients are satisfied after an encounter with this	1	2	3
2.	Initiative — seeks ways to make best use of time. Seeks professional development. Participates in proactive problems solving.	1	2	3
3.	Attendance and Productivity — arrives on time and stays until all patients are discharged. Shows up reliably on scheduled dates. Active participant in provider meetings.	1	2	3
4.	Relationship to Staff — treats support staff with courtesy and respect. Treats colleagues with respect. Is a "team player." Pleasant to work with.	1	2	3
5.	Assists with management of complex/complication management of patients?	Yes	No	NR
6.	Is readily available for consultation?	Yes	No	NR

1.	Credentialing	Satisfactory	Unsatisfactory	NR
2.	Complication Rates	Satisfactory	Unsatisfactory	NR
3.	Occurrence Report/Complaints	Satisfactory	Unsatisfactory	NR

Comments: Trustee to have her on provider team. Med. and patient focused. Advocate for care, public and in practice. Courageous. Protective. Team with training. Active in pt care, improvements. Has integrity, Wife of Marine

Manager's Signature _____ Date 10/21/14

Evaluation Summary
OVERALL JOB RATING
1 – Unacceptable 2 – Needs Improvement 3 – Satisfactory / Productive

Overall Rating: 3

Provider's Comments _____

Signatures

I certify by my signature below that this performance review has been discussed with me. I have read and understand the contents. I understand that my signature does not necessarily indicate agreement with statements made herein.

Physician Signature _____ Date 11/12/14

Medical or Program Director: _____ Date 11/12/14

Chief Executive Officer: _____ Date 11/13/14

CM is a leader among state + local (and national) MDs.
PMF

PHYSICIAN PERFORMANCE REVIEW SUMMARY

Name of Physician: Colleen McNicholas

Physician Annual Performance Review
RHS of PPSLR/SWMO

Definitions of terms used to evaluate work in the following sections:

1	Unacceptable – seldom meets established standards; must improve for continued employment.
2	Needs Improvement — sometimes meets established standard but lacks consistency; seldom exceeds and often falls short of desired results; must improve for continued employment.
3	Satisfactory/Productive — meets and /or exceeds established standards.

Clinical Review: Abortion Services

Date of review: 10/29/14

To be completed by Program Director or Medical Director

1.	Reviews history, lab and other finding. Refers out inappropriate patients	1	2	3
2.	Provides counseling and education as needed.	1	2	3
3.	Establishes effective rapport with staff and patients.	1	2	3
4.	Completes accurate physical assessment, especially in relation to uterine sizing.	1	2	3
5.	Utilizes correct abortion technique.	1	2	3
6.	Demonstrates appropriate use of correct procedures and personal protective equipment.	1	2	3
7.	Performs accurate assessment of POC.	1	2	3
8.	Understands and practices in accordance with RHS of PPSLR protocols.	1	2	3
9.	Accurately and thoroughly document all findings.	1	2	3
10.	Refers for further evaluation as indicated.	1	2	3
11.	Determines appropriate plan for follow-up.	1	2	3
12.	Complication Management.	1	2	3

Comments:

Physician Evaluator Signature [signature] Date 10/29/14

Goals (for next evaluation period)

Americans United for Life

McNicholas

Reproductive Health Services of

Planned Parenthood of the St. Louis Region

Physician NextGen Review

- ✓ Log-in and 5 Point Check
- ✓ Reviewing Medical History
- ✓ 24 Hour Informed Consent
- ✓ EGA Documentation U/S vs LMP
- ✓ Reviewing STI Testing Results and other Labs
- ✓ Reviewing Medication Orders and Completion
- ✓ U/S Approval
- ✓ MedAB Documentation
- ✓ Additional Notes
  - o Time
  - o Content
  - o Name and Credentials

- ✓ IV Sedation Documentation
  - o Vitals and O2Sats through Sedation Grid
- ✓ Pelvic Exam and Uterine Orientation Documentation
- ✓ Surgical Template
  - o Type of Procedure
  - o Start/Stop Time
  - o Details of Procedure
  - o POC Exam
  - o Impression
  - o Plan
  - o Resident Name in Comments Section
  - o Desired BCM
  - o OK

- ✓ Complications
- ✓ Same Day Reaspiration

- ✓ Clinical Assessment of Viability starting at 14 weeks
- ✓ Intent Statements starting at 14 weeks
- ✓ Check Box for Intent starting at 14 weeks
- ✓ D&E Details starting at 14 weeks

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- ✓ IUC Insertion
  - Consents Signed
  - Type of Device with Exp Date and Lot Number
  - Appropriate Candidate
  - Side Effects Discussed
  - Pregnancy Terminated Today
  - Done Under U/S
  - Details of Insertion
  - Ryan Device?
  - OK only once

- ✓ Implant Insertion
  - Consents Signed
  - Type of Device with Exp Date and Lot Number
  - Appropriate Candidate
  - Side Effects Discussed
  - Pregnancy Terminated Today
  - Details of Insertion
  - Ryan Device?
  - OK only once

Date of Review: 12/6/13

Clinician: _____

Reviewer: _____

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REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE SAINT LOUIS REGION
4251 FOREST PARK AVENUE •FIRST FLOOR• SAINT LOUIS MO 63108
(314) 531-7526

Reproductive Health Services
Planned Parenthood of the St. Louis Region

Physician / Clinician Name Colleen McNicholas

Performance & interpretation of ultrasound for pregnancy dating or surgical procedure assistance		X	X
Paracervical Block		X	X
Intravenous Sedation		X	X
Early Surgical Abortion (4 to 5 weeks)		X	X
First Trimester (5 weeks up to 13w6d) with Electric Vacuum Aspiration		X	X
First Trimester Uterine Manual Vacuum Aspiration		X	X
Medication Abortion (through 9 wks)		X	X
Laminaria/Dilapan insertion		X	X
2nd Trimester (≥ 14 weeks) One Day Procedures		X	X
Ultrasound guided feticidal injection		X	X
2nd Trimester Dilation and Evacuation with laminaria insertion (through 22 wks)		X	X
Postabortion IUC placement		X	X
Implanon placement		X	X
May provide 24 hour informed consent as a qualified professional and may supervise other qualified professionals who perform this duty under the direction of the Medical Director		X	

The above listed clinician is granted the above marked privileges

David L. Eisenberg, M.D., MPH
Program Director, Medical Director
Planned Parenthood of the St. Louis Region

7/1/13
Effective Date

RH\forms\drprivileges10/8/05/ 03/12/07/3/09; 7/10, 8/10

Physician Annual Performance Review
RHS of PPSLR/SWMO

Physician:	McNichols
Reviewed By:	Gaulke

Definitions of terms used to evaluate work in the following sections:

1	Unacceptable – seldom meets established standards; must improve for continued employment.
2	Needs Improvement — sometimes meets established standard but lacks consistency; seldom exceeds and often falls short of desired results; must improve for continued employment.
3	Satisfactory/Productive — meets and /or exceeds established standards.

Clinical Review: Abortion Services

To be completed by Program Director or Medical Director

1.	Reviews history, lab and other finding. Refers out inappropriate patients	1	2	3
2.	Provides counseling and education as needed.	1	2	3
3.	Establishes effective rapport with staff and patients.	1	2	3
4.	Completes accurate physical assessment, especially in relation to uterine sizing.	1	2	3
5.	Utilizes correct abortion technique.	1	2	3
6.	Demonstrates appropriate use of correct procedures and personal protective equipment.	1	2	3
7.	Performs accurate assessment of POC.	1	2	3
8.	Understands and practices in accordance with RHS of PPSLR protocols.	1	2	3
9.	Accurately and thoroughly document all findings.	1	2	3
10.	Refers for further evaluation as indicated.	1	2	3
11.	Determines appropriate plan for follow-up.	1	2	3
12.	Complication Management.	1	2	3

Comments:

Physician Evaluator Signature: [signature] Date 10-17-12

Goals (for next evaluation period)

The following section to be completed by the Vice President of Patient Services

Administrative Review

1.	Customer Orientation — understands, commits to and practices a market and customer oriented approach to heal care delivery. Treats clients with respect and non-judgmentally. Clients are satisfied after an encounter with this provider.	1	2	(3)
2.	Initiative — seeks ways to make best use of time. Seeks professional development. Participates in proactive problems solving.	1	2	(3)
3.	Attendance and Productivity — arrives on time and stays until all patients are discharged. Shows up reliably on scheduled dates. Active participant in provider meetings.	1	2	(3)
4.	Relationship to Staff — treats support staff with courtesy and respect. Treats colleagues with respect. Is a "team player." Pleasant to work with.	1	2	(3)

Based on professional communication, collaborative patient management, and/or individual patient care, the above physician performed satisfactorily in the following areas:

1.	Assists with management of complex/complication management of patients?	(Yes)	No	NR
2.	Is readily available for consultation?	(Yes)	No	NR

1.	Credentialing	(Satisfactory)	Unsatisfactory	NR
2.	Complication Rates	(Satisfactory)	Unsatisfactory	NR
3.	Occurrence Report/Complaints	(Satisfactory)	Unsatisfactory	NR

Comments: Allen has been a great addition to the surgical team. Per conversations with providers at ASC she has been a great help for our patients. Dr MN is fine clinician, increasing in her clinical skills, leadership. Asset to our team.

Manager's Signature: Mary Ann Legut VP of Patient Services Date: 10-17-12

Evaluation Summary

OVERALL JOB RATING

1 – Unacceptable 2 – Needs Improvement 3 – Satisfactory / Productive

Overall Rating: 3

Provider's Comments: _____

Signatures

I certify by my signature below that this performance review has been discussed with me. I have read and understand the contents. I understand that my signature does not necessarily indicate agreement with the comments made herein.

Physician Signature: _____
Date: 10/17/12

Medical or Program Director: _____
Date: 10/17/12

Chief Executive Officer: _____
Date: 10/18/12

Physician per review 7.09 / M

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REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE SAINT LOUIS REGION
4251 FOREST PARK AVENUE ·FIRST FLOOR· SAINT LOUIS MO 63108
(314) 531-7526

Reproductive Health Services
Planned Parenthood of the St. Louis Region

Physician / Clinician Name Colleen McNicholas

Performance & interpretation of ultrasound for pregnancy dating or surgical procedure assistance		X
Paracervical Block		X
Intravenous Sedation		X
Early Surgical Abortion (4 to 5 weeks)		X
First Trimester (5 weeks up to 13wod) with Electric Vacuum Aspiration		X
First Trimester Uterine Manual Vacuum Aspiration		X
Medication Abortion (through 9 wks)		X
Laminaria/Dilapan insertion		X
2nd Trimester (≥ 14 weeks) One Day Procedures	X	
Ultrasound guided feticidal injection	X	
2nd Trimester Dilation and Evacuation with laminaria insertion (through 22 wks)	X	
Postabortion IUC placement		X
Implanon placement		X
May provide 24 hour informed consent as a qualified professional and may supervise other qualified professionals who perform this duty under the direction of the Medical Director		X

The above listed clinician is granted the above marked privileges

David L. Eisenberg, MD, MPH
Program Director, Medical Director
Planned Parenthood of the St. Louis Region

7/5/2011
Effective Date

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4401 W 109th St Ste 200
Overland Park, KS 66211
p: 913.312.5100 f: 913.312.3170
www.ppkm.org

Planned Parenthood of Kansas and Mid-Missouri

May 11, 2015

John Langston
Missouri Department of Health and Senior Services
Bureau of Ambulatory Care
PO Box 570
Jefferson City, MO 65102-0570

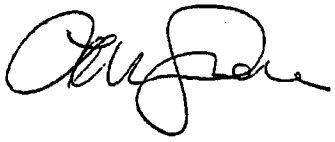
Re: Initial Licensure Survey

Dear Mr. Langston,

Planned Parenthood of Kansas & Mid-Missouri would like to request a waiver to the provision of 19 CSR 30-30.070 (2)(N) which requires that the recovery room shall be of sufficient size to accommodate at least 4 recovery beds or recliners for each procedure room. In order to meet the requirement of three feet of clear space on both sides and at the foot of each recovery bed or recliner, we request that we have 3 recovery recliners instead of 4.

We believe that 3 recovery chairs is sufficient for the planned licensed services and workload. This will in no way impact patient care.

Sincerely,



Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri (PPKM)
Planned Parenthood Advocates of Kansas and Mid-Missouri (PPAKM)

Americans United for Life

Langston, John

Subject: Columbia Licensure

From: Casey, Vicki [mailto:Vicki.Casey@ppkm.org]
Sent: Monday, June 01, 2015 8:44 AM
To: Langston, John
Subject: Columbia Licensure

Hello John,

Attached you will find the documents that were requested at our initial licensure survey. Included are:

1. Credentialing packet for Dr McNicholas:
   a. Appointment and approval by the Governing Body
   b. Dr McNicholas BNDD and DEA certificates
   c. Completed application
   d. Approval of privileges by Dr Moore
2. BNDD and DEA certificates for Columbia facility
3. Waiver/Variance request for recovery room chairs
4. FCSR checks for all staff - The Director of HR is aware that the FCSR must be run on all employees upon hire and has implemented a system to check all employees on a quarterly basis.

We are aware that we will only be approved for medical abortion procedures at this time. We understand that BAC will need to revisit the facility prior to our offering surgical procedures.

Please let me know if there is any other information you need.

Thank you,

Vicki Casey
Health Center Manager
Planned Parenthood of Kansas
& Mid Missouri
711 N Providence Rd
Columbia MO 65203
PH: 913-345-4671
FAX: 573-443-5671
vicki.casey@ppkm.org
PPKM works to ensure that every individual has the knowledge opportunity and freedom to make informed, private decisions about reproductive and sexual health.

[PPKM Logo: Care. No matter what.]<http://www.ppkm.org>

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

July 15, 2015

Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W 109th St, Ste 200
Overland Park, KS 66211

Dear Ms. McQuade:

In accordance with 19 CSR 30-30.070(1), the Missouri Department of Health and Senior Services (DHSS), Section for Health Standards and Licensure (HSL) has **approved** your request for a variance to **19 CSR 30-30.070(2)(N)** for Planned Parenthood of Kansas and Mid-Missouri, 711 N. Providence Road, Columbia, MO 65203, license number 16 ("PPKM"). The variance allows the recovery room to be of sufficient size to accommodate three recovery beds or recliners for its procedure room, rather than four or more, with three feet of clear space on both sides and at the foot of each recovery bed or recliner.

This variance for license number 16 will remain in effect until there is a change in procedure type performed at PPKM; other change in circumstances; or DHSS determines that there is a detrimental impact on the health, safety, or welfare of the patient, staff, or public.

PPKM must submit a copy of this variance letter with its annual licensure renewal. Should you have questions regarding this correspondence, please contact me at (573) 751-6154.

Sincerely,

William Koebel
Assistant Section Administrator
Section for Health Standards and Licensure

WK:sb

Americans United for Life

Missouri Department of Health and Senior Services
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Governor

July 15, 2015

Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W 109th St, Ste 200
Overland Park, KS 66211

Dear Ms. McQuade:

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This variance for license number 16 will remain in effect until there is a change in procedure type performed at PPKM; other change in circumstances; or DHSS determines that there is a detrimental impact on the health, safety, or welfare of the patient, staff, or public.

PPKM must submit a copy of this variance letter with its annual licensure renewal. Should you have questions regarding this correspondence, please contact me at (573) 751-6154.

Sincerely,

William Koebel
Assistant Section Administrator
Section for Health Standards and Licensure

WK:sb

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Planned Parenthood of Kansas and Mid-Missouri

May 11, 2015

John Langston
Missouri Department of Health and Senior Services
Bureau of Ambulatory Care
PO Box 570
Jefferson City, MO 65102-0570

Re: Initial Licensure Survey

Dear Mr. Langston,

Planned Parenthood of Kansas & Mid-Missouri would like to request a waiver to the provision of 19 CSR 30-30.070 (2)(N) which requires that the recovery room shall be of sufficient size to accommodate at least 4 recovery beds or recliners for each procedure room. In order to meet the requirement of three feet of clear space on both sides and at the foot of each recovery bed or recliner, we request that we have 3 recovery recliners instead of 4.

We believe that 3 recovery chairs is sufficient for the planned licensed services and workload. This will in no way impact patient care.

Sincerely,

Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri (PPKM)
Planned Parenthood Advocates of Kansas and Mid-Missouri (PPAKM)

Missouri Department of Health and Senior Services
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

September 25, 2015

Laura McQuade
President and Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W. 109th St., Ste. 200
Overland Park, KS 66211

Re: abortion facility license no. 16-2 (Columbia, Missouri facility)

Dear Ms. McQuade:

State licensure regulations require that physicians performing abortions at abortion facilities must have staff privileges at a hospital within fifteen minutes travel time from the facility. Based on recent action by MU Health Care, effective December 1, 2015, the physician performing abortions at the Columbia facility will no longer have the required privileges. As a result, as of December 1, 2015, the Columbia facility will not be in compliance with state licensure mandates.

Unless the facility satisfies this hospital privileges requirement, the license of the Columbia facility will be revoked on December 1, 2015.

If you have any questions, please contact me at (573) 751-6083.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

November 25, 2015

Via certified mail, no. 7007-0710-0002-2054-4232
Via email to Laura.McQuade@ppkm.org

Laura McQuade
President and Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W. 109th St., Ste. 200
Overland Park, KS 66211

Re: Revocation of abortion facility license no. 16-2 (Columbia, Missouri facility)

Dear Ms. McQuade:

On September 25, 2015, the department notified you that the above abortion facility license would be revoked on December 1, 2015, based on MU Health Care's discontinuance of the facility's physician's privileges.

As stated in the September 25, 2015 notice, state licensure regulations require that physicians performing abortions at abortion facilities have staff privileges at a hospital within fifteen minutes travel time from the facility. Based on MU Health Care's action, effective December 1, 2015, the physician performing abortions at the Columbia facility will no longer have the required privileges. As a result, as of December 1, 2015, the Columbia facility will not be in compliance with state licensure mandates.[1]

To date, the department has not been notified of the facility's ability to satisfy the physician privileges requirement on and after December 1, 2015. Therefore, under Section 197.220, RSMo, the department hereby revokes abortion facility license no. 16-2, effective at the facility's close of business on November 30, 2015.

Pursuant to Section 197.221, RSMo, the facility may file a complaint with the Missouri Administrative Hearing Commission, P.O. Box 1557, Jefferson City, Missouri 65102, within thirty days after the delivery or mailing by certified mail of this decision.

If you have new and pertinent information regarding the facility's ability to satisfy the physician privileges requirement, please let me know as soon as possible.

If you have any questions, please call me at (573) 751-6083.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

[1] *See* 19 CSR 30-30.060(1)(C)4 (physicians performing abortions at abortion facilities must have staff privileges at a hospital within fifteen minutes travel time from the facility); 19 CSR 30-30.060(1)(B)12 (administrator of abortion facility must ensure adherence to Chapter 188, RSMo); and Section 188.080, RSMo (physician performing or inducing abortion who does not have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced shall be guilty of a class A misdemeanor).

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

June 23, 2016

Via certified mail, no. 7014-1820-0000-3523-5021
Via email to Laura.McQuade@ppkm.org and Vicki.Casey@ppkm.org

7014 1820 0000 3523 5021

Laura McQuade
President and Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W. 109th St., Ste. 200
Overland Park, KS 66211

Re: application for licensure of Columbia, Missouri abortion facility

Dear Ms. McQuade:

The department received the application for licensure of the Columbia, Missouri abortion facility located at 711 North Providence Road. The current license for the facility expires on June 30, 2016. As soon as possible, please let me know whether the facility will have a physician with the required privileges[1] by July 1, 2016. If the facility will have such a physician by then, as soon as possible, please provide me with written documentation evidencing the privileges. The department will then work with the facility to schedule an inspection.

The department will not grant the facility a license until the facility has a physician with the required privileges and the department has conducted an inspection to confirm that licensure requirements are met.

If you have any questions, please call me at (573) 751-6083.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

[1]*See* 19 CSR 30-30.060(1)(C)4 (physicians performing abortions at abortion facilities must have staff privileges at a hospital within fifteen minutes travel time from the facility); 19 CSR 30-30.060(1)(B)12 (administrator of abortion facility must ensure adherence to Chapter 188, RSMo); and Section 188.080, RSMo (physician performing or inducing abortion who does not have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced shall be guilty of a class A misdemeanor).

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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 2, 2016

Vicki Casey (vicki.casey@ppgreatplains.org)
Comprehensive Health of Planned Parenthood Great Plains
711 North Providence Road
Columbia, Mo 65203

Re: Comprehensive Health of Planned Parenthood Great Plains – Columbia Survey

Dear Ms. Casey:

The Department received the application for licensure of the Columbia Planned Parenthood location as an abortion facility. Department staff conducted an onsite survey of the location on October 11, 2016 to determine compliance with the terms of the 2010 settlement agreement and applicable statutes and regulations, including the Ambulatory Surgical Center Licensing Law (Section 197.200, RSMo, et seq.) and Chapter 188, RSMo (Regulation of Abortions).

Listed below are items the survey indicated were not in compliance. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued.

19 CSR 30-30.060(1)(B) 12. The administrator shall be responsible for ensuring that the provisions of Chapter 188 RSMo, Regulation of Abortions, are adhered to.

- Sections 188.027 and 188.080, RSMo, require that all physicians performing or inducing abortions have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced. Neither of the facility's two physicians had the required privileges.
- Section 188.047 requires that tissue removed at the time of the abortion be submitted to a pathologist for necessary reporting. The facility did not have a finalized agreement with a pathologist to provide the required services.

19 CSR 30-30.060(1)(C)4. Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility.

- The facility did not have a documented working arrangement with a hospital within the required proximity.
- Neither of the facility's two physicians had the required privileges.

19 CSR 30-30.060(1)(C)1. The medical staff shall develop and, with the approval of the governing body, shall adopt policies governing physician activities in the abortion facility. Medical staff membership shall be limited to physicians.

- The facility policy failed to limit medical staff membership to physicians. The policy stated that advance practice registered nurses could be a member of the medical staff.

19 CSR 30-30.060(1)(C)3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.

- The facility had two physicians on staff. Not all components of a fully credentialed file had been completed for the physicians, including a formal approval of internal facility privileges, appointment to the medical staff, a National Practitioner's Data Bank check, or certifications from BNDD or DEA.

19 CSR 30-30.060(1)(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.

- The facility failed to demonstrate compliance with facility's established Infection Prevention Program, based on Association for the Advancement of Medical Instrumentation standards.
    - The facility did not maintain an autoclave log with the required components tracked (lot number, specific contents of the lot or load, exposure time and temperature, name and initials of the operator, results of biological testing).
    - The facility failed to have the supplies necessary for high level disinfection of vaginal ultrasound probes.

19 CSR 30-30.060(3)(J). Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body.

- The facility did not have a quality assurance program specific to their facility that included the required elements. Facility staff indicated a system-wide QAPI program that had removed elements required by Missouri rules some time before:
    - Intraoperative and postoperative complications
    - All cases that resulted in a length of stay of more than twelve (12) hours, and
    - All cases in which the gestational age was determined to be beyond eighteen (18) weeks.

19 CSR 30-30.060(3)(K). The quality assurance program must show evidence of action taken as a result of the identification of the problems.

- The facility program did not show identification of problems or follow-up of problems.

19 CSR 30-30.060(4)(C). All tissue obtained from abortions, except tissue submitted to a pathologist for analysis, shall be submerged in a preservative solution and shall be transported in a leakproof container to a facility with a waste sterilizer or an incinerator approved by the Department of Natural Resources. If kept for more than twelve (12) hours, all tissue shall be refrigerated.

- The facility failed to produce a final agreement with a pathologist.
- The facility did not have a preservative solution onsite.
- The facility did not have an agreement, approved by the Department of Natural Resources, with a waste sterilizer.
- The facility could not demonstrate whether adequate refrigeration space was available for preservation.

19 CSR 30-30.060(4)(E). Anti-Rh immune globulin therapy shall be given to all Rh negative patients upon completion of the abortion procedure.

- The facility failed to stock the required anti-Rh immune globulin.

19 CSR 30-30.060(3)(I). An emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest and cardiac arrest shall be immediately available to the procedure room and recovery room.

- The facility had two lists of supplies, one for medical and one for surgical abortion procedures. Some necessary medications and supplies were not onsite or had not yet been ordered for either type of procedure (including filter needles, one milliliter syringes, and cervical needles from the surgical supply list).

19 CSR 30-30.070(2)(N). The recovery room . . . shall be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner.

- Required space within the recovery room is not sufficient for at least four (4) recliners with three feet of clear space on both sides and at the foot of each recovery recliner. When this location was previously licensed in 2015, the facility had requested and been granted a variance for three (3) recliners. However, at that time the facility was only approved to provide medication procedures. It is now the facility's intent to also perform surgical procedures. The letter from the department dated July 15, 2015 states that the variance "will remain in effect until there is a change in procedure type performed at [the facility.]" The facility may submit a revised variance request in writing in accordance with 19 CSR 30-30.070(1).

19 CSR 30-30.070(2)(X). A patient toilet with lavatory shall be located convenient to the recovery room. This room shall be equipped with a constant running exhaust.

- The toilet room next to the recovery room has an exhaust fan which runs only when the light to the room is turned on and is activated by the same switch. A constant running exhaust in the patient toilet facility is specifically required in the 2010 settlement agreement (page 17).

Please respond in writing providing evidence/documentation that each of these items has been fully addressed and corrected.

If you have further questions, you may contact our office at 573-751-6083 or via email at the address noted below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

LAW OFFICES
ARTHUR BENSON & ASSOCIATES

ARTHUR BENSON
JAMIE KATHRYN LANSFORD

4006 CENTRAL STREET
KANSAS CITY, MISSOURI 64111-2236
816-531-6565 • 816-531-6688 FAX

EMAIL: abenson@bensonlaw.com
jlansford@bensonlaw.com
WEBSITE www.bensonlaw.com

November 11, 2016

VIA EMAIL: John.Langston@health.mo.gov

John Langston
Administrator, Bureau of Ambulatory Care
Missouri Department of Health and Senior Services
912 Wildwood
PO Box 570
Jefferson City, MO 65102-0570

Dear Mr. Langston:

Comprehensive Health of Planned Parenthood Great Plains ("Planned Parenthood") is in receipt of your letters dated November 2, 2016 regarding DHSS's surveys of Planned Parenthood's Columbia and Kansas City health centers, and we write to provide an initial response to those letters.

First and foremost, we are very disappointed to learn that DHSS intends to enforce Missouri's clearly unconstitutional requirements that facilities that provide abortion be licensed as ambulatory surgical centers and that physicians who provide abortions have local hospital admitting privileges. As we have indicated in previous correspondence to the Department, the United States Supreme Court has made clear in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), *as revised* (June 27, 2016), that these requirements, which do not promote women's health, impose an undue burden on women's access to abortion.

Moreover, while we will provide detailed responses to your letters in due course, we wanted to promptly note a few items for your reconsideration. In particular, with regard to the status of the admitting privileges of the physician at the Brous health center in Kansas City, we have learned that due to a clerical error, those privileges were changed by Menorah Medical Center in 2015 to non-surgical privileges. The hospital has indicated that the physician will need to go through a reappointment process to return his privileges to a clinical/surgical level. That process is underway. However, as you know, this physician does have surgical privileges at Overland Park Regional Medical Center which, while not specifically listed in the 2010 settlement agreement, is the same distance from the Brous health center as Menorah Medical Center and provides similar services. Given the similarity between the two hospitals, any conceivable patient health and safety benefit from having surgical privileges at Menorah Medical Center would be equally met by this physician's existing privileges – especially given that the Brous health center seeks to provide only medication abortion, a non-surgical service.

With regard to the Columbia health center, since the survey was completed Planned Parenthood has secured a written transfer agreement with a hospital within 15 minutes' travel time of this health center. This fulfills the requirement of 19 CSR 30-30.060(1)(C)(4). A number of the remaining items you identified with respect to the Columbia facility seem far from a basis on which to deny licensing. For example, we find it inexplicable that DHSS is deeming the Columbia health center's current waiver regarding the number of recliners in the recovery room insufficient and is requiring a new waiver application, and that DHSS is finding the facility's bathroom fan insufficient, as both these current conditions were approved by DHSS for purposes of the facility's license that recently expired in June 2016 -- and, indeed, have been approved consistently since the settlement agreement was entered, for the provision of both medication and surgical abortion. In addition, several of the items included in the letter regarding the Columbia health center required only minor policy adjustments, which, as you know, were already completed by the time the Brous health center survey occurred (and, presumably, is why those items were not listed in the letter regarding Brous). The remaining items in your letter require only minor administrative adjustments and the stocking of basic supplies necessary for the provision of abortion services, which, as an experienced abortion provider, Planned Parenthood is of course prepared to have in place.

However, it seems that trying to remedy these minor issues would be a waste of Planned Parenthood's resources as long as DHSS continues to enforce the physician privileges requirement. Therefore, please advise us within the next 7 days whether the information provided above regarding Planned Parenthood's physicians' privileges and the Columbia health center's transfer agreement changes DHSS's position about physician privileges.

Thank you for your consideration.

Sincerely,

Arthur Benson

Arthur Benson

Melissa Cohen
Planned Parenthood Federation of America
123 William Street
New York, NY 10038
(212) 261-4649

cc via email:

Nikki Loethen
General Counsel
Missouri Department of Health and Senior Services
Nikki.loethen@health.mo.gov

cc via U.S. Mail:

Chris Koster
Missouri Attorney General
Missouri Attorney General's Office
Supreme Court Building
207 W. High St.
P.O. Box 899
Jefferson City, MO 65102

Daniel Knight
Boone County Prosecuting Attorney
705 E. Walnut St
Columbia, MO 65201-4485

Jean Peters Baker
Jackson County Prosecutor
Jackson County Courthouse
415 E 12th Street
Kansas City, MO 64106

Americans United for Life

Missouri Department of Health and Senior Services
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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 18, 2016

Via email to abenson@bensonlaw.com

Arthur Benson
Arthur Benson & Associates
4006 Central Street
Kansas City, Missouri 64111-2236

Re: Comprehensive Health of Planned Parenthood Great Plains – Kansas City and Columbia facilities

Dear Mr. Benson:

This is in response to your November 11, 2016, letter to me regarding physician privileges at the Kansas City and Columbia, Missouri Planned Parenthood facilities.

Regarding physician privileges at the Kansas City facility, the 2010 settlement agreement states (page 19), "PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060(3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)4."

Your letter states that the Kansas City facility has a physician with surgical privileges at Overland Park Regional Medical Center who would provide medication abortions. Such privileges do not comply with the settlement agreement. Until the facility is in compliance with the privileges requirement of the settlement agreement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Regarding the Columbia facility, your letter states that the facility "has secured a written transfer agreement with a hospital within 15 minutes' travel time" from the facility "which fulfills 19 CSR 30-30.060(1)(C)(4)."[1] The department has not received a copy of this agreement and is therefore unable to confirm whether it complies with the regulation. Regardless, the facility still must comply with 19 CSR 30-30.060(1)(B)12, which states, "The administrator shall be responsible for ensuring that the provisions of Chapter 188 RSMo, Regulation of Abortions, are adhered to." Sections 188.027 and 188.030, RSMo,

[1] Regulation 19 CSR 30-30.060(1)(C)4 states, "Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility."

require that all physicians performing or inducing abortions have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced. Neither of the facility's two physicians have the required privileges. Until the facility is in compliance with the privileges requirement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Additionally, page two of your letter states, "A number of the remaining items you identified with respect to the Columbia facility seem far from a basis on which to deny licensing." To be clear, the department has not denied licensure; the department has identified the deficiencies that must be corrected before licensure could be granted.

If you have additional questions, you may contact our office at (573) 751-6083 or via email at the address below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Planned Parenthood®
Care. No matter what.

Comprehensive Health
4401 W. 109th St Suite 100
Overland Park, KS 66211
p: 913.345.1400 f: 913.345.2820
www.PPGreatPlains.org

Comprehensive Health of
Planned Parenthood Great Plains

June 5, 2017

John Langston
Bureau of Ambulatory Care
MO Department of Health & Senior Services
POB 570
Jefferson City MO 65102

Dear Mr Langston:

Enclosed are our responses to your request for additional clarification regarding the items that were cited at the October 2016 license survey at the Columbia and Patty Brous locations.

Please let me know if you need anything further.

Sincerely,

Amanda Addison
Vice President of Health Services
Planned Parenthood Great Plains
amanda.addison@ppgreatplains.org
PH: 913-345-4659

Received
6/7/17

19 CSR 30-30.060(1)(C)1. The medical staff shall develop and, with the approval of the governing body, shall adopt policies governing physician activities in the abortion facility. Medical staff membership shall be limited to physicians.

- The facility policy failed to limit medical staff membership to physicians. The policy stated that advance practice registered nurses could be a member of the medical staff. **Clarification/question: In the medical staff bylaws, allied health staff are mentioned. The bylaws say only physicians are on medical staff at first, but allied health (page 2 of 9 bylaws) are still referred to as needing a credentialing packet. Can you clarify if that means these individuals are credentialed to be on medical staff or this is just another way to denote the application for some degree of clinical privileges?**

The medical staff bylaws (page 2) refer to the need for clinicians to be credentialed with ARMS who is our liability insurance provider. Please see second bullet point from the bottom of page 2 stating that a certificate of insurance will be provided once the process is complete. This process is called "professional credentialing".
Please see Exhibit 1.

Related Clarification/question: Having privileges approved for the physicians was mentioned in our letter and you mention physicians were approved in your response. However, you didn't list specific privileges or what was approved. [Note, this is specific to privileges granted at your facility, not hospital privileges which was specifically covered by the federal court order.]
Please see Exhibit 2 for Clinical Privileging forms.

19 CSR 30-30.060(1)(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.
The facility failed to have the supplies necessary for high level disinfection of vaginal ultrasound probes. **Clarification/question: The procedure for high level disinfection (HDL) contains a back-up procedure that consists of soaking vaginal probes in a bleach solution. Bleach is not an FDA-approved HLD. For reference see:**https://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm
PPGP removed the use of bleach as a back-up high level disinfectant in the Cleaning the Ultrasound Probe and Care of the Ultrasound Machine Policy. All health centers performing ultrasounds will keep an adequate amount of Resert in stock, so that no back-up is needed. Please see Exhibit 3 for updated policy.

19 CSR 30-30.060(4)(C). All tissue obtained from abortions, except tissue submitted to a pathologist for analysis, shall be submerged in a preservative solution and shall be transported in a leakproof container to a facility with a waste sterilizer or an incinerator approved by the Department of Natural Resources. If kept for more than twelve (12) hours, all tissue shall be refrigerated.

Clarification/question: Your original response states that all tissues (100% of POC) are sent to pathologist so there is no need for the facility to have an agreement with a waste sterilizer. However, there is no information from the pathologist contract anything regarding disposition of tissues. We would like further information in writing on the disposition of tissue by the pathologist to ensure that disposition is by appropriate means and methods. This is part of the abortion provider's overall responsibility to ensure all applicable portions of Chapter 188 is met per CSR 30-30.060(1)(B)(12)

PPGP has conferred with Boyce and Bynum and have been informed that all pathology specimens from abortion are incinerated in accordance with all Missouri laws and regulations. Boyce and Bynum uses an approved waste hauler and an approved incinerator.

Related Clarification/question: On the facility's agreement with the pathology group, it doesn't specifically state that the pathologist will do the state reporting required by chapter 188.047 (Although it does have an overall statement they will comply with state law.) Please clarify in writing that the agreement with the pathology group include all required reporting as required by 188.047 (providing a copy of the pathology report to both the abortion facility as well as the DHSS)

PPGP has confirmed with Boyce and Bynum that they will provide a copy of the pathology report to both the abortion facility and the Department of Vital Statistics within 30 days of the examination of the tissue, as required.

Americans United for Life

Exhibit 1

Licensed Independent Providers Policies & Procedures

Medical Staff

The Medical Staff is a formal organization of physicians who are appointed by the Board of Directors to provide patient care at Comprehensive Health of Planned Parenthood ambulatory surgery centers. The Medical Staff and Board of Directors collaborate to enhance the quality and safety of care, treatment, and services provided to patients. As an ambulatory surgery center licensed by the Kansas Department of Health and Environment in Kansas and Department of Health and Senior Services in Missouri (19 CSR 30-30.060), CHPPGP is required to have a Medical Staff of one or more physicians in Kansas (Kansas Ambulatory Surgery Center Regulations 28-34-50(b)(1) and three or more physicians in Missouri.

Medical Staff Membership

All physicians who work at CHPPGP are Medical Staff members. At PPGP/CHPPGP, the credentialing application is also the application for CHPPGP Medical Staff membership.

Medical Staff Bylaws for the CHPPGP ASC Medical Staff are located in the PPFA Medical Director Orientation Manual (2014) and Clinician Performance Monitoring Toolkit (2013).

CHPPGP Medical Staff Meetings occur quarterly immediately following the All-Staff meeting and are led by the Medical Director with administrative assistance to draft the agenda, send meeting invitations, record attendance and draft the minutes. The minutes are approved by the Medical Director. The CHPPGP Medical Staff members may invite other licensed independent providers (LIP), including advance practice registered nurses and physician assistants, to attend the Medical Staff meeting.

Medical Director

The Medical Director supervises all aspects of medical care at PPGP/CHPPGP. The Medical Director's responsibilities include performing or delegating the following:

- Leads the CHPPGP Medical Staff
- Oversees family planning, abortion and colposcopy programs
- Implements and updates the Medical Standards and Guidelines (MS&Gs)
- Develops or approves medical and clinical policies & procedures
- Ensures provider orientation, education, privileging, periodic chart review, and annual Ongoing Professional Practice Evaluation (OPPE) occur
- Establishes relationships within the medical community and participates in formulation of the referral list
- Serves as Laboratory Director
- Leads the Quality/ Peer Review Committee
- Reviews significant medical incidents in STARS and makes recommendations
- Assists legal counsel in responding to State regulatory investigations

- Serves as the collaborative practice agreement physician in Kansas and Missouri
- Serves as the Ultrasound Director to ensure staff and physician training and competence
- Serves on the PPGP/CHPPGP Quality/Risk Management Steering Committee

Professional Credentialing Policy

PPGP/CHPPGP demonstrates its commitment to being a health care leader that provides a consistently high level of quality care to the community by ensuring that all professional staff possess the appropriate licensure, education and relevant training. PPGP/CHPPGP requires its licensed independent providers (LIPs), at a minimum, to possess the credentials delineated in the ARMS Clinical Performance Monitoring Toolkit (2013).

The Director of CQRM uses the PPFA/ARMs credentialing service to verify the credentials of all physicians, Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Registered Nurses (RNs) and Licensed Social Workers (LSWs). Verification is sought to confirm that the provider has the education, training, skill sets, judgment, character, integrity, ability to work with others, and practice patterns to provide patient care at PPGP/CHPPGP. Credentialing occurs at the time of hire. Re-credentialing occurs every 3 years thereafter. This process is called "professional" credentialing to distinguish it from the process of "insurance" credentialing, performed by the finance and billing department.

Credentialing Procedure

The Director of CQRM will:

- Coordinate with Human Resources so that new providers are given the credentialing application immediately at the time of hire because it takes from 15 to 30 days to verify credentials. The process must start immediately in order to be completed before orientation ends. A new LIP should not care for patients independently until credentials are verified or insurance carriers may not pay for the care.
- All new physicians, APRNs, PAs, RNs and LSWs must complete the credentialing application and return it with a curriculum vitae and their DEA number, if relevant, within 5 days of hire. All gaps in employment must be explained. ARMS requires the professional credentialing process to have begin within 10 days of hire in order for the provider to see patients. If the provider cannot work because he/she did not return the application on time, PPGP/CHPPGP may not pay the provider until the application is submitted.
- Upload the application and CV to the credentialing service.
- Complete the ARMS request for a certificate of insurance (COI) naming the provider.
- Purchase special professional liability insurance for Certified Nurse Midwives (CNMs) and physician assistants who practice in Kansas. The most affordable option has been to buy insurance through our agent with KaMMCO. CNMs and

physician assistants must have special insurance because Kansas makes them pay into the Kansas Health Care Stabilization Fund.

- Notify the insurance credentialer that the provider is onboarding and fill out the shared provider spreadsheet with NPI number, DEA number, date of birth, etc. The spreadsheet is here: Q drive > Credentialing folder. The insurance credentialer will enter the LIP into the CAQH database and credential the LIP with third party payers.
- Query the National Provider Data Bank (NPDB) and download the provider's report.
- Draft collaborative practice agreements (CPA) for APRNs in Kansas, Missouri and Arkansas. Best practice is for the APRN to sign contracts with both the collaborating physician and a backup collaborating physician.
- Remind APRNs who will be prescribing testosterone in Missouri to submit an application for Controlled Substance Prescriptive Authority and a Notice of Delegated Prescriptive Authority for Controlled Substances with the Missouri State Board of Nursing. Send the CPA physician 10% of charts and 20% of controlled substance prescriptions every 2 weeks for review if required by State law.
- Download the verified credential report when it is ready.
- Review report for adverse events and, if necessary, request additional information to understand them.
- Give the practitioner's report to Human Resources to put into the provider's file.
- Give the RN or LSW's report to the VP Clinical Services.
- If the new physician works in the Kansas ASC or a Missouri abortion facility, remind the Board of Directors to approve the Medical Staff appointment as required by Kansas and Missouri regulations.
- Note: The new clinician orientation process and checklist are located in the Operations Manual section on Staff Standards.

Re-Credentialing Process

ARMS requires all physicians, APRNs, PAs. RNs, and LSWs to re-credential every 3 years. The Director of CQRM will:

- Annually, request the ARMS credentialing service to provide a spreadsheet of all credentialed staff and note which ones are due for the 3-year re-credentialing.
- Ask these staff to complete the re-credentialing application and return it.
- Upload the completed application to the credentialing service.
- Check the practitioner's name in the NPDB.

Credential Maintenance Policy

It is the policy of PPGP/CHPPGP that each professional has the responsibility to renew her/his own licenses and certifications, that licensed staff do not provide patient care if a mandatory license or certification lapses, and that professionals who allow a license or certification to lapse are subject to disciplinary action. If a LIP provides patient care after their certification or license lapses, and the insurance company (including

Medicaid) denies the claim due to the lapse, the LIP may be asked to reimburse PPGP/CHPPGP for denied claim.

Credential Maintenance Procedure

PPGP/CHPPGP has a process to ensure that its health care providers maintain required licensure and certification.

- As a courtesy, professionals may be reminded to renew licenses and certifications 60 and 30 days before expiration. PPGP/CHPPGP assumes no responsibility if a license or certification expires.
- In Missouri, APRNs must:
  - fax their renewed certification to the Missouri State Board of Nursing
    - The fax number is: **573-522-2143**
  - save the fax confirmation receipt.
  - After sending the fax, APRNs will telephone the Missouri State Board of Nursing to confirm the Board received their certification renewal.
    - The phone number to call is: **573.751.0681**
  - The APRN will document this phone call and save the documentation because the Missouri State Board of Nursing has denied receiving several faxed certifications in 2015 and 2016.
- The Director of CQRM will search on line to make sure the appropriate licensing entity posted the renewal.
- The Director of CQRM will notify the VP of Health Clinical Services and the Revenue Cycle Director if a license or certification expires (Medicaid may not reimburse care provided by an LIP with expired credentials).

Privileging Policy

It is the policy of PPGP/CHPPGP that only those health professionals who by state law, education and training are qualified to perform a particular clinical function are allowed to do so. Specialized services must only be provided by clinicians who are trained and demonstrate proficiency in those specific areas. Examples include, but are not limited to, performing ultrasound, colposcopy and Norplant and IUC insertions and removals. Determining the competency of each clinician is the responsibility of the Medical Director for physicians or Lead Clinician for APRNs and PAs.

Privileging Process

Newly Hired Practitioner – all newly hired physicians and APRN/PAs must undergo a period of supervised practice called proctoring. Proctoring is required regardless of pay status (employed, contracted, volunteer), length of experience prior to joining, or length of service (ex. employed 5 years and begins providing colposcopies). Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and is delegated to the Lead Clinician for PA/APRNs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form located in the PPFA Clinician Performance Monitoring Toolkit.

Practitioners Seeking Additional Privileges will be proctored by a practitioner who is privileged to perform the procedure. Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and Lead Clinician for APRN/PAs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form, located in the PPFA Clinician Performance Monitoring Toolkit.

Ongoing Professional Practice Evaluation Policy

It is PPGP/CHPPGP's policy to conduct ongoing professional practice evaluation (OPPE) at least annually to ensure clinicians are providing and documenting care consistent with the MS&Gs and the PPGP/CHPPGP mission. If OPPE reveals adverse data, the Medical Director will develop a performance improvement plan that may include altering the provider's privileges, additional proctoring, education, discipline, or termination, in order to ensure patient safety.

Ongoing Professional Practice Evaluation Procedure

PA/APRN OPPE

The Medical Director is responsible for APRN/PA OPPE but may delegate the review to the Lead Clinician. The Lead Clinician will report all findings to the Medical Director for final determination of competency. Competency will be evaluated within 3 months of hire and annually at a minimum.

Methods of review include:

- Chart Audit: The Lead Clinician will audit at least 10 patient charts for the PA/APRN annually and as needed.
- Observation: The Lead Clinician will observe the APRN/PA during orientation and annually. Areas of observation will include history taking, patient education, physical assessment, infection control, patient management, and charting.
- Microscopy: The Lead Clinician will assess Vaginal Wet Mount Microscopy accuracy semi-annually and will evaluate competency annually. At the annual evaluation, microscopy skills will be observed. In addition, at least 5 slides will be reviewed by the APRN/PA and the Lead Clinician with an expectation of 80% agreement. Semi-annually, the APRN/PA will be tested on reading at least 4 microscope photos with an expectation of 100% accuracy.
- Training and Meetings: PA/APRNs are expected to participate in PPGP/CHPPGP Leadership Team Meetings and training opportunities.
- Referral Protocol: The Lead Clinician will review APRN/PA compliance with the referral protocol via annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.
- Pap Protocol: PA/APRNs will be reviewed for compliance with the abnormal pap protocol. Review will be by annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.

Lead Clinician OPPE

The Medical Director will perform the Lead Clinician's OPPE based on the above review methods. Additionally, the Lead Clinician will be evaluated on her/his oversight of the provision of clinic medical services, including APRN/PAs, medical assistants, RNs, LPNs, and student PA/APRNs. The Lead Clinician will be evaluated on how well she/he works with the clinic managers to communicate any changes in medical care and protocols to clinic staff.

Physician OPPE

The Medical Director is responsible for performing physician OPPE. Competency will be evaluated within 3 months of hire and annually. The Medical Director will employ the following methods of review:

- Observation: Areas of review will include surgical technique, communication with staff, professional rapport with patients and infection control.
- Chart Audit: Patient care chart audits of at least 10 charts will be performed annually and as needed to assure compliance with the MS&Gs. All areas of service the physician provides will be included. Areas of review will include consent, history, lab, assessment, plan, and referral.
- Risk Management: Physician complication statistics will be compiled annually and reviewed for trends by the Medical Director, staff physicians, Director of CHPPGP, and Director of Quality and Risk Management. An annual complication rate will be included in the annual physician review with an expectation of less than 2% complication rate.
- Training and Meetings: Physician is expected to participate in CME meetings and training opportunities.

Medical Director OPPE

The Medical Director's OPPE will be performed by an outside physician consultant. Additionally, the Medical Director will be evaluated on how well he/she fulfills the Medical Director job description.

Ultrasound Quality Improvement Program OPPE

PPGP has an ongoing ultrasound quality improvement program for all staff that performs ultrasounds that includes:

- Initial training
- Proctoring
- Privileging
- Monitoring
- Ongoing proficiency

All staff who perform ultrasounds for abortion care will demonstrate competence initially by completing the Ultrasound Privileging form (located in the PPFP Clinician Performance Monitoring Toolkit (2013), watching the CAL ultrasound videos, proctering an annual observation and annual chart review of 10 random chart by the Lead Clinician.

Quality/Peer Review Policy

Where OPPE occurs annually and examine the provider's competence, the Quality / Peer Review Committee (QPRC) meets quarterly and examines unwanted clinical outcomes for trends and opportunities for improvement. It is the policy of PPGP/CHPPGP for the QPRC to review all unwanted patient outcomes. The process is protected under state and federal physician peer review, quality improvement, and patient safety statutes. Each participant should sign a confidentiality agreement and not discuss cases outside of the QPRC meeting to maintain protection from legal discovery.

As an ambulatory surgery center licensed by the Kansas Department of Health and Environment, the PPGP/CHPPGP is required to have a written risk management plan that is approved by the Board of Directors and submitted to KDHE annually (K.S.A. 65-492 and K.A.R. 28-52-1 through 28-52-4). The Risk Management Plan requires establishing a quarterly Peer Review meeting with at least 2 physicians. If there are fewer than 2 physicians on the CHPPGP ASC Medical Staff, KDHE requires the Peer Review Committee to procure an outside physician consultant.

Missouri also requires ambulatory surgery centers to have a Risk Management Plan. These plans are located: Q drive > Public Departments > Clinical Services > ALL Manuals> shortcut.

QPRC Procedure

- The QPRC is composed of the Medical Director and at least 1 additional physician.
- APRN/PAs are typically invited to attend the meetings and contribute.
- The CHPPGP Surgical Nurse Managers/CHPPGP Ambulatory Surgery Center Risk Managers attends and presents cases.
- The Director of CQRM drafts the agenda and records minutes.
- The QPRC members review the care provided and ask:
    - Was the complication or unwanted outcome known to be associated with the procedure
    - Was the complication recognized in a timely manner
    - Was the complication treated appropriately
    - Was the standard of care met
    - Was the complication part of a larger trend, and
    - Is there an opportunity for providers to improve the quality and safety of patient care?

The QPRC functions under the constructs of the Just Culture algorithm where the main focus is on learning and improving safety.

For CHPPGP cases, if the physicians find that the provider failed to meet the standard of care and the patient was harmed or was likely to have been harmed, the QPRC is required to report the case to KDHE. It is the policy of CHPPGP not to report cases to KDHE that did not occur in the ambulatory surgery center.

The state of Missouri requires abortion facilities in the state to report all complications. This requirement is described in the Missouri Risk Management Plan.

The Medical Director or Lead Clinician will assist practitioners who may require performance improvement activities.

The Medical Director or delegate will contact legal counsel where there may be an incident that is reportable to the state licensing agency or National Practitioner Data Bank.

Medical Director and Board of Director Review Schedule

Board of Directors appoint new CHPPGP Medical Staff Members for KS & MO	Review at Board meeting after completion of orientation, credentialing & privileging	Kansas Ambulatory Surgery Center Regulation 28-34-53
Board of Directors approve CHPPGP Risk Management Plan for KS & MO	Annually	Kansas Ambulatory Surgery Center Regulation 28-34-50(b)(1)
Medical Director & Lead Clinician approve MS&Gs	Annually	Required by PPFA as stated in Administrative chapter 1.

Resources

- Comprehensive Health of Planned Parenthood Great Plains Ambulatory Surgery Center Quality and Risk Management Plan (including pharmacy, lab and infection prevention)
- ARMS Credentials Verification: A Reference Guide for Planned Parenthood Affiliates
- PPFP Medical Director Orientation Manual (2014)
- PPFP Clinician Performance Monitoring Toolkit (2013)
- Kansas ASC Risk Management Planned Parenthood of Kansas and Mid-Missouri
- Missouri Abortion Facility Risk Management Plan
- Forms:
    - Clinician Skills Checklist: Proctoring Form
    - Clinical Privilege Form
    - Annual Clinician Performance Evaluation
    - Chart Review Form
    - OSHA evaluation

Exhibit 2

CLINICAL PRIVILEGING FORM

Colleen McNicholas has been granted clinical privileges for the following:

Date	Service	Signature of Medical Director or physician designee
4/15/15	X 1st trimester Surgical Abortion	
4/15/15	X Abortion pill	
4/15/15	X 2nd trimester Surgical abortion	
4/15/15	X Conscious Sedation	
	☐ Transabdominal Tubal Sterilization	
	☐ Hysteroscopic Tubal Sterilization	
	☐ Vasectomy	
	☐ Hysteroscopy	
	☐ LEEP	
	☐ Cryotherapy	
	☐ Colposcopy	
	☐ Endometrial Biopsy	
	☐ Vulvar Biopsy	
	☐ Fine Needle Aspiration	
	☐ Simple Cyst Aspiration	
4/15/15	X IUC Insertion	
4/15/15	X Implanon insertion	
	☐ Implant removal	
4/15/15	X Standard U/S (Abortion)	
4/15/15	X Limited U/S (Abortion)	
	☐ Standard U/S (Pregnancy)	
4/15/15	☐ Limited U/S (Pregnancy)	
	X Limited U/S for IUC localization	
	☐ Standard U/S (GYN)	
	☐	
	☐	
	☐	

List any formal training clinician received for service(s) noted above:

Service	Year	Length of Training	Didactic component	Clinical Component
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no

I have read and understand the _____ protocol. I agree to practice in accordance with this protocol when I am caring for clients at PHCM.

Clinician

Date

CLINICAL PRIVILEGING FORM

Ron Yeomans has been granted clinical privileges for the following:

Date	Service	Signature of Medical Director or physician designee
12/08/14	☑ Surgical Abortion	
	☐ Surgical Female Sterilization	
	☐ Essure	
	☐ Male Sterilization	
	☐ Hysteroscopy	
	☐ LEEP	
	☐ Cryotherapy	
	☐ Colposcopy	
	☐ Endometrial Biopsy	
	☐ Vulvar Biopsy	
	☐ Fine Needle Biopsy	
	☐ IUD insertion	
	☐ Implanon insertion and removal	
	☐ Norplant removal	
	☐ Standard U/S (Abortion)	
12/08/14	☑ Limited U/S (Abortion)	
	☐ Standard U/S (Pregnancy)	
	☐ Limited U/S (Pregnancy)	
	☐ Limited U/S for IUD localization	
	☐ Standard U/S (GYN)	
12/08/14	☑ Medical Abortion	
	☐ _____	
	☐ _____	

List any formal training clinician received for service(s) noted above:

Service	Year	Length of Training	Didactic component	Clinical Component
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no

I have read and understand PP CHPPGP protocol. I agree to practice in accordance with this protocol when I am caring for clients at _____.

Ronald K. Yeomans, MD
Clinician

12/8/14
Date

Americans United for Life

Exhibit 3

Planned Parenthood®
Care. No matter what.

Planned Parenthood Great Plains

Policy: CLEANING THE ULTRASOUND PROBE AND CARE OF THE ULTRASOUND MACHINE

Originator: Kristin Metcalf-Wilson DNP, WHNP-BC

Approval Date: 04/01/2017

Policy:

Ultrasound machines constitute a significant resource investment for the agency. Although care must be taken with all aspects of the machine, the probes are especially delicate. Be sure to refer to the owner's manual/manufacturer's recommendations provided with the machine being used in the center.

The level of disinfection needed in between patients is determined by the route of scanning and the type of tissue contact. Transvaginal ultrasound constitutes endocavity scanning with mucous membrane contact and thus requires high level disinfection of the probe between patients. Although the use of probe covers may minimize probe contamination, the failure rate is surprisingly high and their use does not remove the need for high level disinfection. Abdominal scanning over intact skin poses little contamination risk, making a lower level of disinfection acceptable.

Process in the Clinics:

Starting the day

- Inspect all cords and probes for possible defects that may pose a safety hazard to the operator or patients.
- Ensure that any cords are tucked out of the way and uncoiled. Rolling over, stepping on or continuous tangling of the probe cords may damage the wires contained within the cords, causing imaging problems.
- Ensure proper supplies are available: ultrasound gel, non-latex sheaths and/or condoms for use with the vaginal probe, drape sheets, mild soap, cleaning agent(s) and soaking container, indicator strips and log for results, 2x4 labels, soft cloths, Resert XL HLD solution, and a timer.

General cleaning considerations

- All probes should be disconnected from the machine before they are cleaned to minimize safety hazards (i.e. shock to the operator, water damage to the machine).
- Although paper towels may be used to gently remove a soiled sheath, they should not routinely be used in any other part of the cleaning process. Paper towels are like sandpaper to the probe's delicate membrane surface.

- A soft cotton pile or microfiber cloth/towel should be used in any of the cleaning routines that follow. Although there are some disposable disinfecting wipes on the market, they do not provide the high level disinfection needed for the vaginal probe.
- A new cloth/towel is needed for every step in the process, so one should have access to at least three cloths per every scan. The microfiber towels (available at Costco or most automotive parts stores) can easily be cut into smaller squares (4 per towel) without fraying of the material.
- Launder cloths/towels according state guidelines and in a manner that maintains their softness. Towels that have lost their softness should be discarded as they may harm the probe membrane. Microfiber towels should not be exposed to fabric softener as it diminishes their absorptive abilities.

Resert XL HLD Solution for high level disinfection

Cleaning agents vary in the length of time needed to achieve high level disinfection, cost, and associated materials needed for the safe use of the cleaning agent. In an effort to provide high level disinfection in the least complicated manner and the shortest possible period of time, Resert is used to disinfect the probe.

Resert XL HLD is a ready to use, high level disinfecting solution. Unlike other high level disinfecting agents, it is virtually odorless, requiring no special ventilation, non-staining, and does not require special precautions (dilution or deactivation) for disposal.

Once poured into the soaking chamber, Resert XL HLD solution is good for up to 21 days of reuse provided that the minimum recommended concentration (MRC) of 1.5% is present, as verified by the approved indicator strips. A log of indicator results should be maintained.

The original open date should be recorded on the Resert XL HLD solution bottle using labels. The manufacturer's information indicates that the solution is good in the original container until the expiration date listed on the container. The soaking chamber should also have a center-applied label that lists the date the solution was poured into it, solution expiration date and the anticipated 21 day end of life date. At the start of every day, the solution must be tested with a Verify Chemical Monitoring Strip for Resert Solutions. Record the results of the test in the Resert Log. If the solution fails the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin. The solution should be covered at the end of every day. Please note that the color of the solution may change to light amber over time. This is not an indication of a problem as long as the MRC is verifiable.

Steris, maker of Resert XL HLD, suggests the following procedure for the using Verify Chemical Monitoring Strip for Resert Solutions:

- Ensure that the bottle of indicator strips is labeled with an open date. The strips expire 90 days from the open date or on the listed expiration date, whichever date comes first.
- Remove an indicator strip from the bottle. Dip the indicator pad into the soaking solution for 2 seconds, blot any excess by touching the edge of the pad to a paper towel, and then lay flat with the indicator pad facing up for 90 seconds, using a timer to monitor. Compare strip to color reference on the bottle.
- At the end of 90 seconds, read and record the result in the appropriate log. A "pass" is indicated by a color change from yellow to black. A "fail" is indicated by any blue or yellow remaining on the pad after 90 seconds.

- If the solution "fails" the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin.
- Controls should be run upon opening any new bottle of indicator strips.
    - For the positive control, dispense approximately 30mL of Resert XL HLD solution from an unopened bottle into a clean container. Run three test strips as per usual routine. All three strips must "pass."
    - For the negative control, dispense 15mL of Resert XL HLD solution from an unopened bottle into a clean plastic bottle, add 15mL of tap water to the bottle, and gently mix. Run three test strips as per usual routine. All three test strips must "fail."
    - If all six strips result as expected, the new bottle of Verify Chemical Monitoring Strip for Resert Solution may be used until the listed expiration date, whichever comes first. Be sure to record the open and controls run date on the bottle itself and in the log.
- Check state and local disposal regulations. Any expired or "failing" solution may be disposed of by flushing down the drain with water. The original container should be triple rinsed with water before tossing. Consult the MSDS for first aid measures. The indicator strips contain dye that may stain once activated but otherwise require no special precautions.

Cleaning of the vaginal probe

- Begin the day by testing the soaking solution to ensure that the MRC is met and verify that it is within the 21 day reuse range. Document results in the appropriate log.
- After scanning, unplug the probe from the machine and set the connector (plug) in the holder on the mounting kit that houses the soaking cup.
- Remove the contaminated probe cover with a paper towel and discard. Rinse the probe under water to remove any excess gel.
- Gently and thoroughly clean the probe using mild dish soap and a soft cloth, then rinse with running water, and dry with a clean soft cloth. Drying is important because it prevents progressive dilution of the soaking solution.
- Gently immerse the probe in the Resert XL HLD solution for eight minutes, using a timer to verify appropriate time interval. The immersion should include the entire transducer shaft (up to the ring that divides the handle from the transducer shaft) but none of the handle. See diagram in the manufacturer's probe brochure. The probe should not be left soaking any longer than the recommended eight minutes, as this may damage the probe covering.
- Rinse well with running water and dry using a clean soft cloth.
- Plug the connector back into the machine. The probe is now ready for use with the next patient.
- Note the aforementioned cleaning regimen requires the use of three soft cloths/towels per each probe disinfection and at least five minutes to elapse on the timer before calling back a new patient.

Cleaning of the abdominal probe

Abdominal probes should be cleaned and disinfected but do not generally require high level disinfection between patients.

- Remove any excess gel from the sides of the abdominal probe with a clean soft cloth. Spray probe with an ultrasound disinfectant detergent such as T-Spray and wipe thoroughly with a clean soft cloth.
- For this process, the abdominal probe does not need to be disconnected from the ultrasound machine.

Cleaning at the end of the day

Perform an extra cleaning of the probes at the end of the day to ensure equipment is left in optimal condition and ready to use. The Resert XL HLD solution should be covered. Launder any used cloths according to center and state guidelines.

Miscellaneous cleaning and service

Dust all areas of the machine twice per month or as needed with a lightly damp cloth. This is most easily accomplished with the machine turned off. The trackball may be removed and cleaned as need.
The screen may be cleaned using an alcohol swab and a soft cloth or Kimwipes. This task is best performed with the machine turned off and by working in quadrants so as to avoid streaking.

Annual maintenance of the machines may be provided by a manufacturer representative.

If trouble call service is needed, please contact agency resources to determine if the issue can be solved internally (IT or other staff) or requires a service call from the manufacturer. Contact a member of leadership to determine if service charges from the manufacturer are acceptable as the minimum trip charges are quite high.

Exporting files for storage

Files should be exported to CD/DVD or deleted from ultrasound machine hard drive storage before 50% of the hard drive capacity is exceeded. Failure to do so may result in sluggish performance of the machine.

Reference: ARMS Infection Prevention Manual

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for Life

The Department received the supplemental information you sent in regards to the remaining items cited at the October 2016 licensure survey of the Kansas City location (Brous Center). We request some additional clarification/information as follows:

19 CSR 30-30.0601(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.

- The facility failed to establish a traffic pattern in the decontamination/sterilization room that prevented cross contamination between contaminated and clean instrument processing. **Clarification/question: It is not entirely clear in the photos you supplied where the decontamination is being performed. Is it still be done in the same room as during the October 2016 visit? If the room remains the same as during our visit, have you have moved the autoclave to the center of the room so decontamination is carried out as staff enters, so traffic does not crossover and increase the chance of cross contamination? There was some discussion during our visit that the room might be relocated, or at least traffic patterns altered. Could you clarify? It might help to include a rough diagram of any changes made to the room or location or traffic pattern.**
- Decontamination is currently being performed in the same room as the October 2016 visit. The autoclave has been moved to the end of the counter and staff perform decontamination upon entering the room, so that cross contamination does not occur. Please see Exhibit 1, which is a diagram that illustrates the current traffic pattern.

- The facility failed to establish a policy for the process of high level disinfection of semi-critical instruments and equipment using OPA (ortho-phthalaldehyde) solution that included cleaning, disinfecting, rinsing, drying and storage.
Clarification/question: The procedure for high level disinfection (HDL) contains a back-up procedure that consists of soaking vaginal probes in a bleach solution. Bleach is not an FDA-approved HLD. For reference see:
https://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm
PPGP removed the use of bleach as a back-up high level disinfectant in the Cleaning the Ultrasound Probe and Care of the Ultrasound Machine Policy. All health centers performing ultrasounds will keep an adequate amount of Resert in stock, so that no back-up is needed. Please see Exhibit 2 for updated policy.

- The facility failed to ensure staff followed the policy for utilization of PPE (personal protective equipment) during decontamination of soiled instruments. The appropriate PPE was not available in the instrument decontamination/sterilization room. **Clarification/question: We did not see that this item was addressed; did we overlook it in your response? If so, please note where it is found.**
A picture of the available PPE was included in the letter dated 5/16/17 (Exhibit B) along with staff training materials. PPEs available for staff include face masks,

utility gloves. aprons and goggles/eye protection. Please see Exhibit 3 for an updated picture of PPE.

- The facility failed to follow safe medication practices by storing medications in the decontamination/sterilization room, and storing medications side by side in the refrigerator and locked cabinet with laboratory reagents and miscellaneous supplies. **Clarification/question: Blood Glucose reagents may be stored with medications but other reagents and lab specimens cannot be stored with medications (typically needs to be different refrigerator, not different shelf in the same refrigerator.)**
- PPGP has purchased an additional refrigerator to store reagents and lab specimens. Medication will be stored in a separate refrigerator. Please see Exhibit 4 for receipt for purchase of refrigerator.

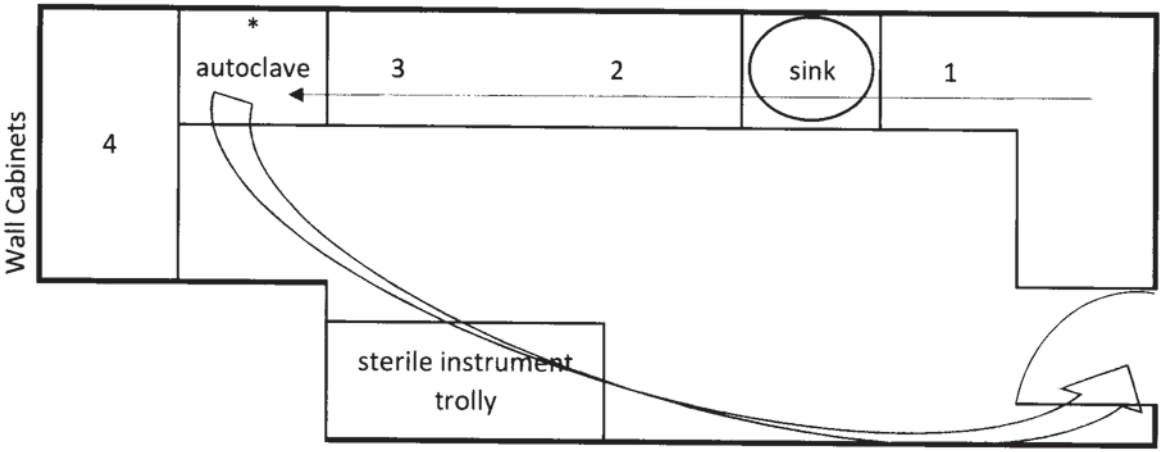
- The facility stored supplies in corrugated boxes in the decontamination/sterilization room. **Clarification/question: We did not see that this item was addressed; did we overlook it in your response? If so, please note where it is found.** PPGP addressed corrugated cardboard boxes in the 5/16/17 letter in Exhibit F, which was pictures showing that there was no corrugated cardboard in the decontamination/sterilization room. Currently supplies are being removed from corrugated cardboard boxes and stored in Rubbermaid containers. Please see additional attached pictures in Exhibit 5.

Americans United for Life

Exhibit 1

Americans United for Life

Traffic Pattern in Instrument Processing Room at Patty Brous



1 Soiled instrument deposited in basin
instruments washed in sink
2 instrument drying rack
3 clean area
4 clean instruments wrapped & labeled for autoclave
autoclave unloaded and sterile instruments are placed on wheeled trolly and taken to instrument storage areas
note: autoclave cannot be moved to opposite wall because there is no electric outlet there and the autoclave cord is not long enough to snake along wall to nearest electric outlet. Autoclave will not fit underneath the wall cabinets. Patty Brous will only offer medical abortions so there will be very few instruments to process.

Exhibit 2

Planned Parenthood
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Planned Parenthood Great Plains

Policy: CLEANING THE ULTRASOUND PROBE AND CARE OF THE ULTRASOUND MACHINE

Originator: Kristin Metcalf-Wilson DNP, WHNP-BC

Approval Date: 04/01/2017

Policy:

Ultrasound machines constitute a significant resource investment for the agency. Although care must be taken with all aspects of the machine, the probes are especially delicate. Be sure to refer to the owner's manual/manufacturer's recommendations provided with the machine being used in the center.

The level of disinfection needed in between patients is determined by the route of scanning and the type of tissue contact. Transvaginal ultrasound constitutes endocavity scanning with mucous membrane contact and thus requires high level disinfection of the probe between patients. Although the use of probe covers may minimize probe contamination, the failure rate is surprisingly high and their use does not remove the need for high level disinfection. Abdominal scanning over intact skin poses little contamination risk, making a lower level of disinfection acceptable.

Process in the Clinics:

Starting the day

- Inspect all cords and probes for possible defects that may pose a safety hazard to the operator or patients.
- Ensure that any cords are tucked out of the way and uncoiled. Rolling over, stepping on or continuous tangling of the probe cords may damage the wires contained within the cords, causing imaging problems.
- Ensure proper supplies are available: ultrasound gel, non-latex sheaths and/or condoms for use with the vaginal probe, drape sheets, mild soap, cleaning agent(s) and soaking container, indicator strips and log for results, 2x4 labels, soft cloths, Resert XL HLD solution, and a timer.

General cleaning considerations

- All probes should be disconnected from the machine before they are cleaned to minimize safety hazards (i.e. shock to the operator, water damage to the machine).
- Although paper towels may be used to gently remove a soiled sheath, they should not routinely be used in any other part of the cleaning process. Paper towels are like sandpaper to the probe's delicate membrane surface.

- A soft cotton pile or microfiber cloth/towel should be used in any of the cleaning routines that follow. Although there are some disposable disinfecting wipes on the market, they do not provide the high level disinfection needed for the vaginal probe.
- A new cloth/towel is needed for every step in the process, so one should have access to at least three cloths per every scan. The microfiber towels (available at Costco or most automotive parts stores) can easily be cut into smaller squares (4 per towel) without fraying of the material.
- Launder cloths/towels according state guidelines and in a manner that maintains their softness. Towels that have lost their softness should be discarded as they may harm the probe membrane. Microfiber towels should not be exposed to fabric softener as it diminishes their absorptive abilities.

Resert XL HLD Solution for high level disinfection

Cleaning agents vary in the length of time needed to achieve high level disinfection, cost, and associated materials needed for the safe use of the cleaning agent. In an effort to provide high level disinfection in the least complicated manner and the shortest possible period of time, Resert is used to disinfect the probe.

Resert XL HLD is a ready to use, high level disinfecting solution. Unlike other high level disinfecting agents, it is virtually odorless, requiring no special ventilation, non-staining, and does not require special precautions (dilution or deactivation) for disposal.

Once poured into the soaking chamber, Resert XL HLD solution is good for up to 21 days of reuse provided that the minimum recommended concentration (MRC) of 1.5% is present, as verified by the approved indicator strips. A log of indicator results should be maintained.

The original open date should be recorded on the Resert XL HLD solution bottle using labels. The manufacturer's information indicates that the solution is good in the original container until the expiration date listed on the container. The soaking chamber should also have a center-applied label that lists the date the solution was poured into it, solution expiration date and the anticipated 21 day end of life date. At the start of every day, the solution must be tested with a Verify Chemical Monitoring Strip for Resert Solutions. Record the results of the test in the Resert Log. If the solution fails the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin. The solution should be covered at the end of every day. Please note that the color of the solution may change to light amber over time. This is not an indication of a problem as long as the MRC is verifiable.

Steris, maker of Resert XL HLD, suggests the following procedure for the using Verify Chemical Monitoring Strip for Resert Solutions:

- Ensure that the bottle of indicator strips is labeled with an open date. The strips expire 90 days from the open date or on the listed expiration date, whichever date comes first.
- Remove an indicator strip from the bottle. Dip the indicator pad into the soaking solution for 2 seconds, blot any excess by touching the edge of the pad to a paper towel, and then lay flat with the indicator pad facing up for 90 seconds, using a timer to monitor. Compare strip to color reference on the bottle.
- At the end of 90 seconds, read and record the result in the appropriate log. A "pass" is indicated by a color change from yellow to black. A "fail" is indicated by any blue or yellow remaining on the pad after 90 seconds.

- If the solution "fails" the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin.
- Controls should be run upon opening any new bottle of indicator strips.
    - For the positive control, dispense approximately 30mL of Resert XL HLD solution from an unopened bottle into a clean container. Run three test strips as per usual routine. All three strips must "pass."
    - For the negative control, dispense 15mL of Resert XL HLD solution from an unopened bottle into a clean plastic bottle, add 15mL of tap water to the bottle, and gently mix. Run three test strips as per usual routine. All three test strips must "fail."
    - If all six strips result as expected, the new bottle of Verify Chemical Monitoring Strip for Resert Solution may be used until the listed expiration date, whichever comes first. Be sure to record the open and controls run date on the bottle itself and in the log.
- Check state and local disposal regulations. Any expired or "failing" solution may be disposed of by flushing down the drain with water. The original container should be triple rinsed with water before tossing. Consult the MSDS for first aid measures. The indicator strips contain dye that may stain once activated but otherwise require no special precautions.

Cleaning of the vaginal probe

- Begin the day by testing the soaking solution to ensure that the MRC is met and verify that it is within the 21 day reuse range. Document results in the appropriate log.
- After scanning, unplug the probe from the machine and set the connector (plug) in the holder on the mounting kit that houses the soaking cup.
- Remove the contaminated probe cover with a paper towel and discard. Rinse the probe under water to remove any excess gel.
- Gently and thoroughly clean the probe using mild dish soap and a soft cloth, then rinse with running water, and dry with a clean soft cloth. Drying is important because it prevents progressive dilution of the soaking solution.
- Gently immerse the probe in the Resert XL HLD solution for eight minutes, using a timer to verify appropriate time interval. The immersion should include the entire transducer shaft (up to the ring that divides the handle from the transducer shaft) but none of the handle. See diagram in the manufacturer's probe brochure. <u>The probe should not be left soaking any longer than the recommended eight minutes, as this may damage the probe covering.</u>
- Rinse well with running water and dry using a clean soft cloth.
- Plug the connector back into the machine. The probe is now ready for use with the next patient.
- Note the aforementioned cleaning regimen requires the use of three soft cloths/towels per each probe disinfection and at least five minutes to elapse on the timer before calling back a new patient.

Cleaning of the abdominal probe

Abdominal probes should be cleaned and disinfected but do not generally require high level disinfection between patients.

- Remove any excess gel from the sides of the abdominal probe with a clean soft cloth. Spray probe with an ultrasound disinfectant detergent such as T-Spray and wipe thoroughly with a clean soft cloth.
- For this process, the abdominal probe does not need to be disconnected from the ultrasound machine.

Cleaning at the end of the day

Perform an extra cleaning of the probes at the end of the day to ensure equipment is left in optimal condition and ready to use. The Resert XL HLD solution should be covered. Launder any used cloths according to center and state guidelines.

Miscellaneous cleaning and service

Dust all areas of the machine twice per month or as needed with a lightly damp cloth. This is most easily accomplished with the machine turned off. The trackball may be removed and cleaned as need.
The screen may be cleaned using an alcohol swab and a soft cloth or Kimwipes. This task is best performed with the machine turned off and by working in quadrants so as to avoid streaking.

Annual maintenance of the machines may be provided by a manufacturer representative.

If trouble call service is needed, please contact agency resources to determine if the issue can be solved internally (IT or other staff) or requires a service call from the manufacturer. Contact a member of leadership to determine if service charges from the manufacturer are acceptable as the minimum trip charges are quite high.

Exporting files for storage

Files should be exported to CD/DVD or deleted from ultrasound machine hard drive storage before 50% of the hard drive capacity is exceeded. Failure to do so may result in sluggish performance of the machine.

Reference: ARMS Infection Prevention Manual

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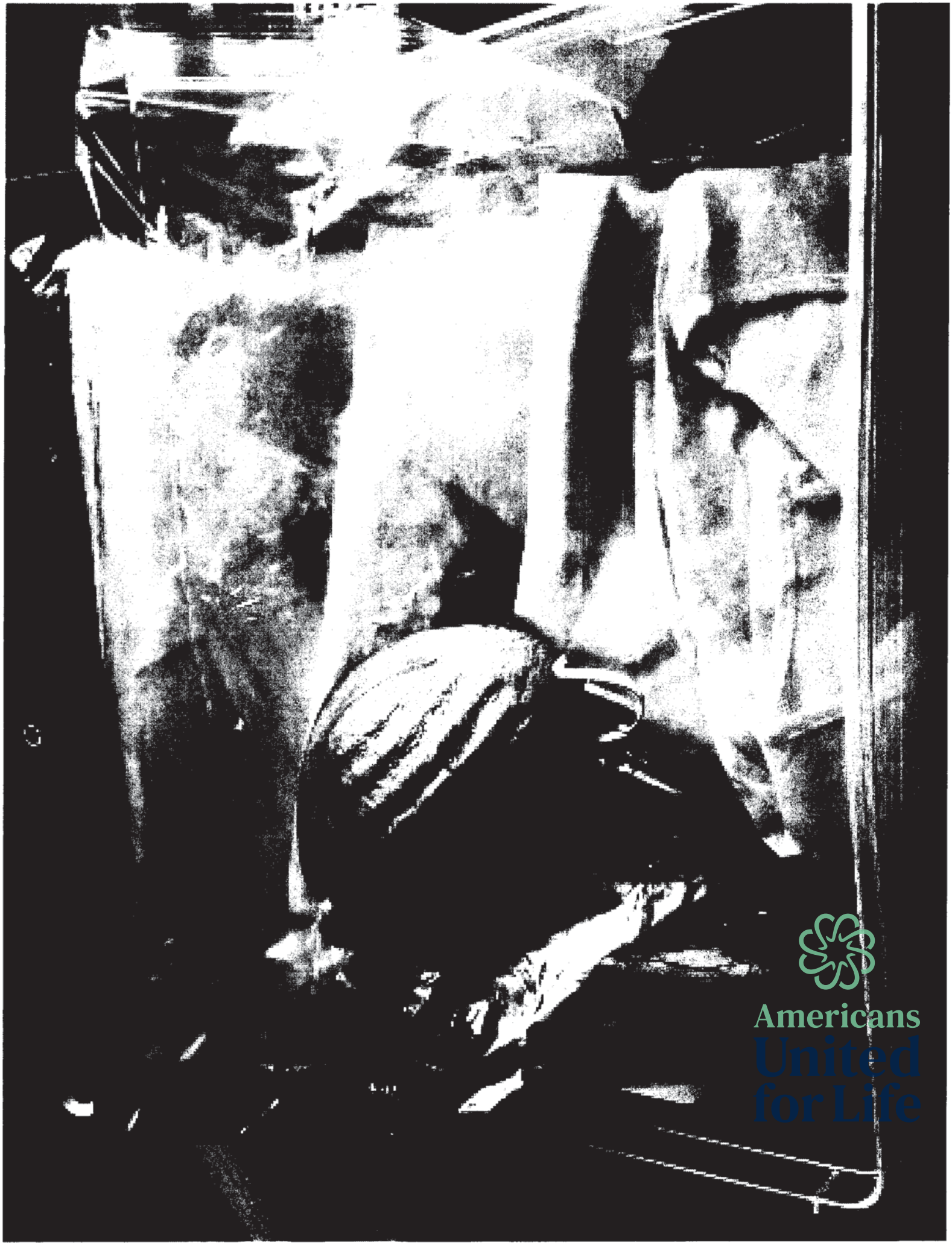
Exhibit 3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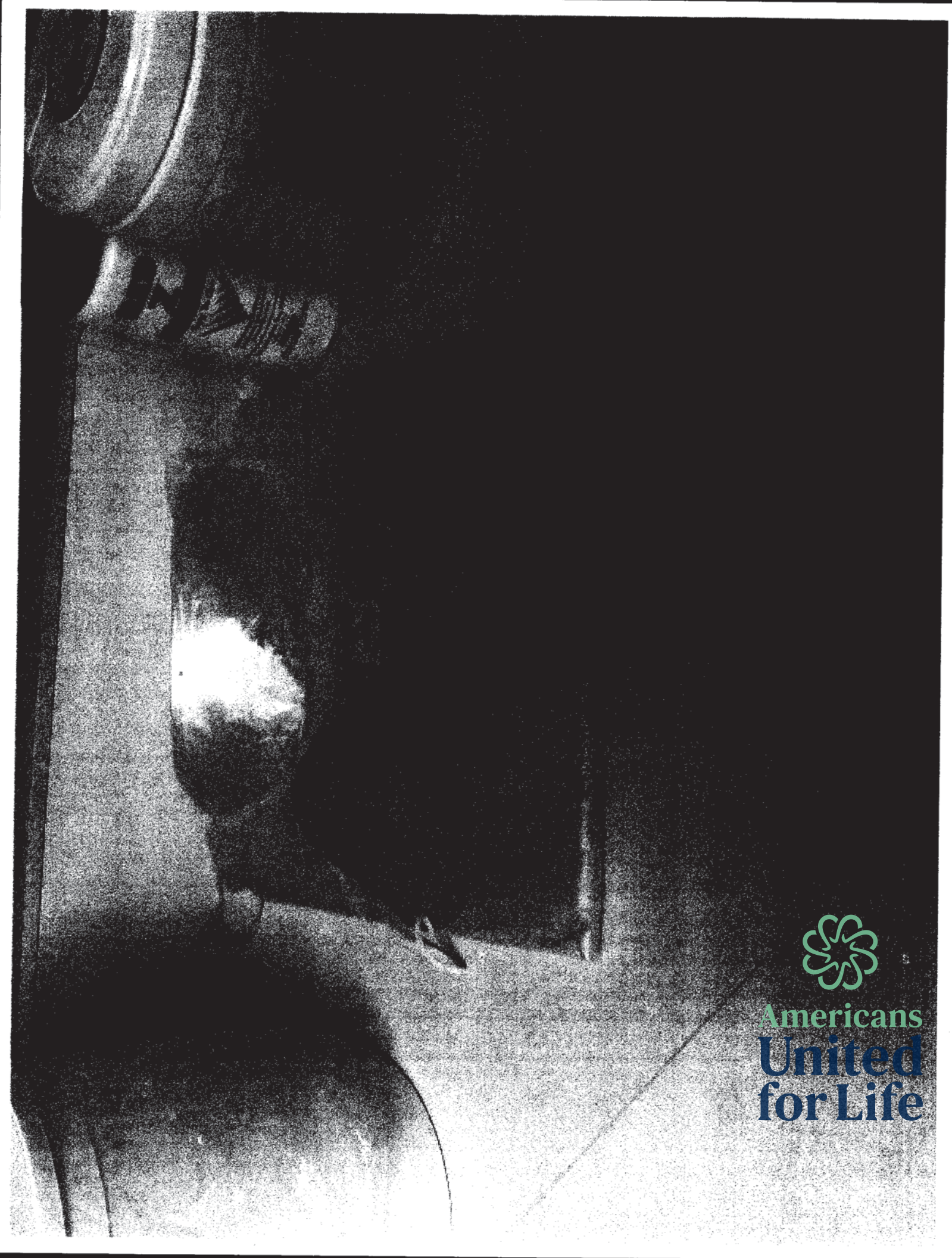
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Exhibit 4

See back of receipt for your chance to win $1000

ID #: 7LQVQ5VZOFH

Walmart

Save money. Live better.

(913) 296 - 0890
MANAGER MICHELLE MORALES
5150 ROE BLVD
ROELAND PARK KS 66205
STR 02490 OPR 009075 TE# 08 TR# 05694
1.7 C.F. BLK 083632100739 79.84 X
2YR RPL PLAN 060638822149 7.00 X
POWER STRIP 082721400568 19.84 X
SUBTOTAL 106.68
TAX 1 10.225 % 10.91
TOTAL 117.59
AMEX TEND 117.59
AMERICAN EXPRESS *** **** ***1 004 I 0
APPROVAL # 865650
REF # 000100269652
TRANS ID - 000965625981489

AID A0000000250108O1
TC 9A69C25A43CBEC85
TERMINAL # 285365921
*Signature Verified

05/31/17 12:46:20
CHANGE DUE 0.00
ITEMS SOLD 3
TC# 6060 6671 3618 8577 1945 0

Low Prices You Can Trust. Every Day.
05/31/17 12:46:20
CUSTOMER COPY

Americans United for Life

Exhibit 5


Americans
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for Life

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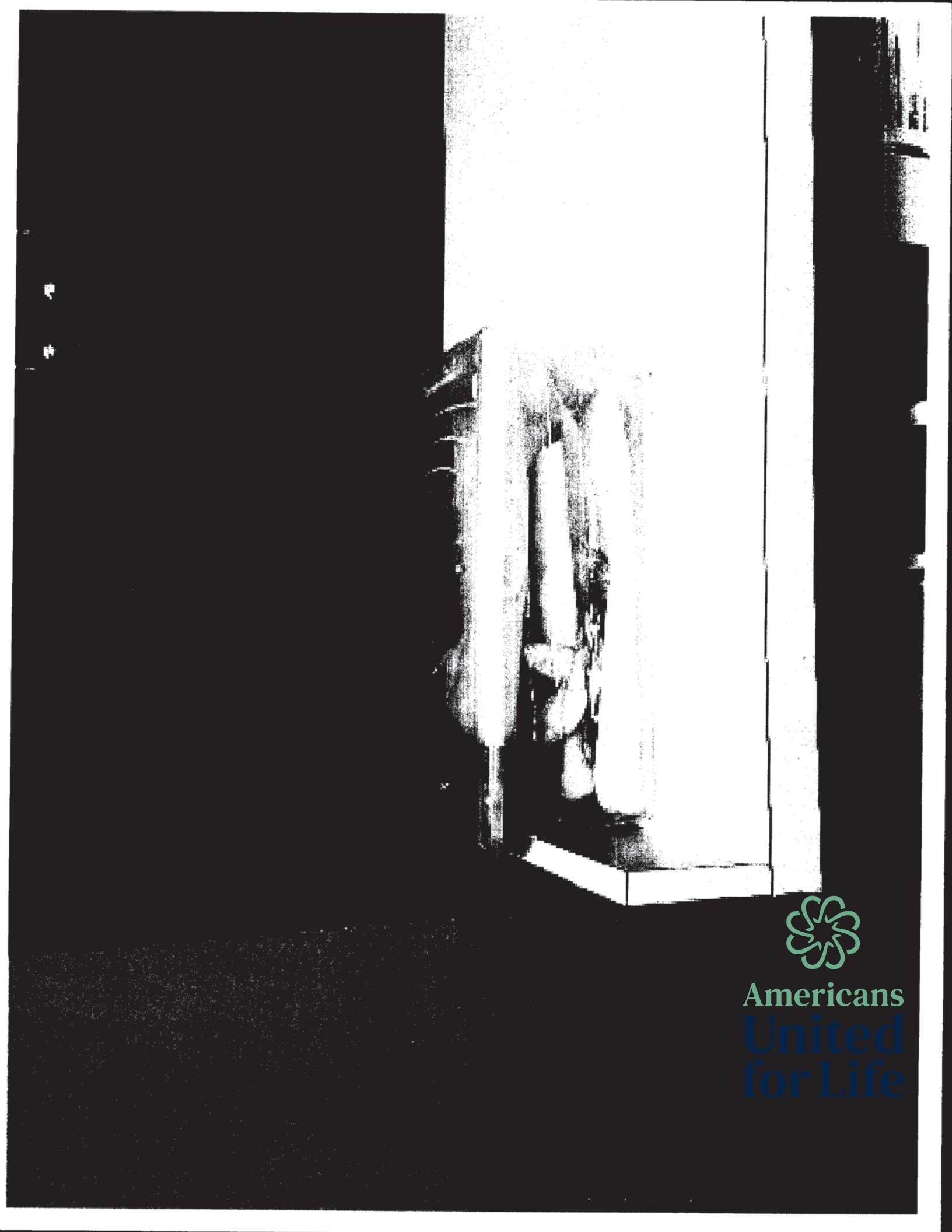
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for Life

Planned Parenthood®
Care. No matter what.

Comprehensive Health
4401 W. 109th St Suite 100
Overland Park, KS 66211
p: 913.345.1400 f: 913.345.2820
www.PPGreatPlains.org

Comprehensive Health of
Planned Parenthood Great Plains

May 16, 2017

John Langston
Bureau of Ambulatory Care
MO Department of Health & Senior Services
POB 570
Jefferson City MO 65102

Dear Mr Langston:

Please find attached our responses to the items that were found noncompliant at the October 2016 survey done at Comprehensive Health – Columbia location.

1. Credentialing packet for Dr Coleen McNicholas and Dr Ronald Yeomans
   Exhibit 1
   - Corporate Board Resolution/Medical Staff Approval to Practice (Physicians)
   - BNDD Certifications
   - DEA Certifications
   - Copies of National Practitioner's Data Bank check
   -
2. Limiting medical staff membership to physicians only
   Exhibit 2
   - Licensed Independent Providers Policies & Procedure from PPGP/CH Operations Manual

3. Pathology Contract
   Exhibit 3
   - Finalized pathology contract with Boyce & Bynum

4. Infection Control
   Exhibit 4
   - Copy of Autoclave Log
   - Packing slips for high level disinfecting supplies for ultrasound vaginal probe
   - Copy of PPGP/CH procedure for high level disinfecting

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RECEIVED MAY 17 2017

5. Quality Assurance Program
   Exhibit 5
   - Copy of Quality Assurance & Risk Management Plan containing all elements required by Missouri abortion regulations
   -

6. Pathology –
   Exhibit 6
   - Copies of packing slips for 10% Formalin preservative solution
   - Picture of refrigerator to be used only for POC specimens

   **All POC's will be sent to pathology for disposal. No agreement with a waste sterilizer approved by the Dept of Natural Resources needed.

7. Anti-Rh Immune Globulin Therapy
   Exhibit 7
   - McKesson packing slip for MicroGAM

8. Supplies
   Exhibit 8
   - Supply list for medical and surgical abortions attached
   - Crash Cart checklist

9. Physician Hospital Privileges
   Section 060(1)(C)(4) of the organizational and management of abortion facilities is enjoined. Sections 188.027 and 188.080, RSMo, are enjoined.

10. Recovery Room Chairs
    070(2)(N) physical facility requirements are enjoined.

11. Recovery Room Exhaust Fan
    070(2)(X) physical facility requirements are enjoined.

Please let me know if you need anything further.

Sincerely,

Amanda Addison
Vice President of Health Services
Planned Parenthood Great Plains
amanda.addison@ppgreatplains.org
PH: 913-345-4659

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EXHIBIT 1

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Comprehensive Health of
Planned Parenthood Great Plains

CORPORATE BOARD RESOLUTION

Medical Staff Approval to Practice - Physicians

Based on successful credentialing by Medversant and skills assessment performed by the Medical Director or designee, the following provider(s) have been approved by the Comprehensive Health medical committee for privileges to practice at Comprehensive Health. These name(s) are respectfully submitted to the Comprehensive Health of Planned Parenthood Great Plains, Inc. Board of Directors for approval to practice. The following medical staff has agreed to conform with the bylaws of the governing authority and practice within the scope of the medical policies and protocols approved by the Medical Director.

I HEREBY CERTIFY that at a meeting of the Board of Directors of **Comprehensive Health of Planned Parenthood of Great Plains, Inc. (CHPPGP)**, a corporation organized and existing under and by virtue of the laws of the State of Missouri, held on the 6th day of December, 2016, at which said meeting a quorum was present and acting throughout, the following resolution was adopted and ever since has been and now is in full force and effect.

RESOLVED, that the Board of Directors of CHPPGP hereby approves the following medical staff to practice medicine:

Dr. Orrin Moore, MD
Overland Park, KS
Kansas City, MO

Dr. Laura Arrowsmith, DO
Tulsa, OK

Dr. Irene Bettinger, MD
Overland Park, KS
Kansas City, MO

Dr. Andrew Broselow, MD
Oklahoma City, OK
Wichita, KS

Dr. Elizabeth Campbell, DO
Tulsa, OK
Fayetteville, AR

Dr. Stephanie Ho, MD
Dr. Colleen McNicholas, DO
Columbia, MO

Dr. Jennifer Nelson, MD
Oklahoma City, OK

Dr. Clyde Rodgers, Jr. MD
Little Rock, AR

Dr. Ronald Yeomans, MD
Overland Park, KS
Wichita, KS
Kansas City, MO
Columbia, MO

In witness whereof, I have hereunto set my hand this 6th day of December 2016.

Marjorie Sable
Marjorie Sable
Board Secretary

MCNICHOLAS, COLLEEN P
711 PROVIDENCE ROAD
COLUMBIA, MO 65203-4357-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM5595573	01-31-2019	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	PRACTITIONER	10-06-2015

MCNICHOLAS, COLLEEN P
711 PROVIDENCE ROAD
COLUMBIA, MO 65203-4357

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM5595573	01-31-2019	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	PRACTITIONER	10-06-2015

MCNICHOLAS, COLLEEN P
711 PROVIDENCE ROAD
COLUMBIA, MO 65203-4357

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Form DEA-223 (4/07)

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	MCNICHOLAS, COLLEEN PATRICIA
BNDD Number:	2500031106
Description:	DOCTOR OF OSTEOPATHY
Street Address:	711 N PROVIDENCE RD
City/State/Zip:	COLUMBIA, MO 65203.4357
Phone Number:	573-443-0427
Registration Effective:	11/11/2016
Registration Expires:	11/30/2017
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	

Validation Date of the Registration is: 11/18/2016

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000117415258
Process Date: 12/06/2016
Page: 1 of 1
MCNICHOLAS, COLLEEN
For authorized use by:
PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

MCNICHOLAS, COLLEEN - ONE-TIME QUERY RESPONSE

Practitioner Name:	MCNICHOLAS, COLLEEN
Date of Birth:	12/10/1980 **Gender:** FEMALE
Organization Name:	PPGP
Work Address:	4401 W 109TH ST STE 200, OVERLAND PARK, KS 66211-1303
Social Security Number:	***-**-2828
License:	OSTEOPATHIC PHYSICIAN (DO)

Statutes Queried:	Title IV; Section 1921; Section 1128E
Query Type:	This is a One-Time query response. Your organization will only receive future reports on this practitioner if another query is submitted.
Entity Name:	PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI (DBID ending in ...54)
Authorized Submitter:	JANET SMITH, DIRECTOR OF COMPLIANCE AND QUALITY RISK, (913) 345-4609

The following report types have been searched:

Medical Malpractice Payment Report(s):	No Reports	Health Plan Action(s):	No Reports
State Licensure Action(s):	No Reports	Professional Society Action(s):	No Reports
Exclusion or Debarment Action(s):	No Reports	DEA/Federal Licensure Action(s):	No Reports
Government Administrative Action(s):	No Reports	Judgment or Conviction Report(s):	No Reports
Clinical Privileges Action(s):	No Reports	Peer Review Organization Action(s):	No Reports

---------- **No Reports Found** ----------

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FY6465012	05-31-2019	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5.	PRACTITIONER	12-01-2016

YEOMANS, RONALD N (MD)
711 N. PROVIDENCE ROAD
COLUMBIA, MO 65203-4357

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	YEOMANS, RONALD N
BNDD Number:	2500037739
Description:	MEDICAL DOCTOR
Street Address:	711 N PROVIDENCE RD
City/State/Zip:	COLUMBIA, MO 65203.4357
Phone Number:	573-875-4177
Registration Effective:	11/3/2016
Registration Expires:	11/30/2017
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	11/3/2016

Validation Date of the Registration is: 4/28/2017

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

NATIONAL PRACTITIONER DATA BANK

NPDB

P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000114513116
Process Date: 10/18/2016
Page: 1 of 1
YEOMANS, RONALD
For authorized use by:
PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

YEOMANS, RONALD - ONE-TIME QUERY RESPONSE

Practitioner Name:	YEOMANS, RONALD
Date of Birth:	12/08/1940 **Gender:** MALE
Organization Name:	PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI
Organization Type:	AMBULATORY SURGICAL CENTER (391)
Work Address:	4401 W 109TH ST STE 200, OVERLAND PARK, KS 66211-1303
Social Security Number:	***-**-3082 **NPI:** 1417018557
License:	PHYSICIAN (MD), 04-14015, KS

Statutes Queried:	Title IV; Section 1921; Section 1128E
Query Type:	This is a One-Time query response. Your organization will only receive future reports on this practitioner if another query is submitted.
Entity Name:	PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI (DBID ending in ...54)
Authorized Submitter:	JANET SMITH, DIRECTOR OF COMPLIANCE AND QUALITY RISK, (913) 345-4609

The following report types have been searched:

Medical Malpractice Payment Report(s):	No Reports	Health Plan Action(s):	No Reports
State Licensure Action(s):	No Reports	Professional Society Action(s):	No Reports
Exclusion or Debarment Action(s):	No Reports	DEA/Federal Licensure Action(s):	No Reports
Government Administrative Action(s):	No Reports	Judgment or Conviction Report(s):	No Reports
Clinical Privileges Action(s):	No Reports	Peer Review Organization Action(s):	No Reports

---------- **No Reports Found** ----------

Americans United for Life

EXHIBIT 2

Americans United for Life

Licensed Independent Providers Policies & Procedures

Medical Staff

The Medical Staff is a formal organization of physicians who are appointed by the Board of Directors to provide patient care at Comprehensive Health of Planned Parenthood ambulatory surgery centers. The Medical Staff and Board of Directors collaborate to enhance the quality and safety of care, treatment, and services provided to patients. As an ambulatory surgery center licensed by the Kansas Department of Health and Environment in Kansas and Department of Health and Senior Services in Missouri (19 CSR 30-30.060), CHPPGP is required to have a Medical Staff of one or more physicians in Kansas (Kansas Ambulatory Surgery Center Regulations 28-34-50(b)(1) and three or more physicians in Missouri.

Medical Staff Membership

All physicians who work at CHPPGP are Medical Staff members. At PPGP/CHPPGP, the credentialing application is also the application for CHPPGP Medical Staff membership.

Medical Staff Bylaws for the CHPPGP ASC Medical Staff are located in the PPFA Medical Director Orientation Manual (2014) and Clinician Performance Monitoring Toolkit (2013).

CHPPGP Medical Staff Meetings occur quarterly immediately following the All-Staff meeting and are led by the Medical Director with administrative assistance to draft the agenda, send meeting invitations, record attendance and draft the minutes. The minutes are approved by the Medical Director. The CHPPGP Medical Staff members may invite other licensed independent providers (LIP), including advance practice registered nurses and physician assistants, to attend the Medical Staff meeting.

Medical Director

The Medical Director supervises all aspects of medical care at PPGP/CHPPGP. The Medical Director's responsibilities include performing or delegating the following:

- Leads the CHPPGP Medical Staff
- Oversees family planning, abortion and colposcopy programs
- Implements and updates the Medical Standards and Guidelines (MS&Gs)
- Develops or approves medical and clinical policies & procedures
- Ensures provider orientation, education, privileging, periodic chart review, and annual Ongoing Professional Practice Evaluation (OPPE) occur
- Establishes relationships within the medical community and participates in formulation of the referral list
- Serves as Laboratory Director
- Leads the Quality/ Peer Review Committee
- Reviews significant medical incidents in STARS and makes recommendations
- Assists legal counsel in responding to State regulatory investigations

- Serves as the collaborative practice agreement physician in Kansas and Missouri
- Serves as the Ultrasound Director to ensure staff and physician training and competence
- Serves on the PPGP/CHPPGP Quality/Risk Management Steering Committee

Professional Credentialing Policy

PPGP/CHPPGP demonstrates its commitment to being a health care leader that provides a consistently high level of quality care to the community by ensuring that all professional staff possess the appropriate licensure, education and relevant training. PPGP/CHPPGP requires its licensed independent providers (LIPs), at a minimum, to possess the credentials delineated in the ARMS Clinical Performance Monitoring Toolkit (2013).

The Director of CQRM uses the PPFA/ARMs credentialing service to verify the credentials of all physicians, Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Registered Nurses (RNs) and Licensed Social Workers (LSWs). Verification is sought to confirm that the provider has the education, training, skill sets, judgment, character, integrity, ability to work with others, and practice patterns to provide patient care at PPGP/CHPPGP. Credentialing occurs at the time of hire. Re-credentialing occurs every 3 years thereafter. This process is called "professional" credentialing to distinguish it from the process of "insurance" credentialing, performed by the finance and billing department.

Credentialing Procedure

The Director of CQRM will:

- Coordinate with Human Resources so that new providers are given the credentialing application immediately at the time of hire because it takes from 15 to 30 days to verify credentials. The process must start immediately in order to be completed before orientation ends. A new LIP should not care for patients independently until credentials are verified or insurance carriers may not pay for the care.
- All new physicians, APRNs, PAs, RNs and LSWs must complete the credentialing application and return it with a curriculum vitae and their DEA number, if relevant, within 5 days of hire. All gaps in employment must be explained. ARMS requires the professional credentialing process to have begun within 10 days of hire in order for the provider to see patients. If the provider cannot work because he/she did not return the application on time, PPGP/CHPPGP may not pay the provider until the application is submitted.
- Upload the application and CV to the credentialing service.
- Complete the ARMS request for a certificate of insurance (COI) naming the provider.
- Purchase special professional liability insurance for Certified Nurse Midwives (CNMs) and physician assistants who practice in Kansas. The most affordable option has been to buy insurance through our agent with KaMMCO. CNMs and

physician assistants must have special insurance because Kansas makes them pay into the Kansas Health Care Stabilization Fund.

- Notify the insurance credentialer that the provider is onboarding and fill out the shared provider spreadsheet with NPI number, DEA number, date of birth, etc. The spreadsheet is here: Q drive > Credentialing folder. The insurance credentialer will enter the LIP into the CAQH database and credential the LIP with third party payers.
- Query the National Provider Data Bank (NPDB) and download the provider's report.
- Draft collaborative practice agreements (CPA) for APRNs in Kansas, Missouri and Arkansas. Best practice is for the APRN to sign contracts with both the collaborating physician and a backup collaborating physician.
- Remind APRNs who will be prescribing testosterone in Missouri to submit an application for Controlled Substance Prescriptive Authority and a Notice of Delegated Prescriptive Authority for Controlled Substances with the Missouri State Board of Nursing. Send the CPA physician 10% of charts and 20% of controlled substance prescriptions every 2 weeks for review if required by State law.
- Download the verified credential report when it is ready.
- Review report for adverse events and, if necessary, request additional information to understand them.
- Give the practitioner's report to Human Resources to put into the provider's file.
- Give the RN or LSW's report to the VP Clinical Services.
- If the new physician works in the Kansas ASC or a Missouri abortion facility, remind the Board of Directors to approve the Medical Staff appointment as required by Kansas and Missouri regulations.
- Note: The new clinician orientation process and checklist are located in the Operations Manual section on Staff Standards.

Re-Credentialing Process

ARMS requires all physicians, APRNs, PAs. RNs, and LSWs to re-credential every 3 years. The Director of CQRM will:

- Annually, request the ARMS credentialing service to provide a spreadsheet of all credentialed staff and note which ones are due for the 3-year re-credentialing.
- Ask these staff to complete the re-credentialing application and return it.
- Upload the completed application to the credentialing service.
- Check the practitioner's name in the NPDB.

Credential Maintenance Policy

It is the policy of PPGP/CHPPGP that each professional has the responsibility to renew her/his own licenses and certifications, that licensed staff do not provide patient care if a mandatory license or certification lapses, and that professionals who allow a license or certification to lapse are subject to disciplinary action. If a LIP provides patient care after their certification or license lapses, and the insurance company (including

Medicaid) denies the claim due to the lapse, the LIP may be asked to reimburse PPGP/CHPPGP for denied claim.

Credential Maintenance Procedure

PPGP/CHPPGP has a process to ensure that its health care providers maintain required licensure and certification.

- As a courtesy, professionals may be reminded to renew licenses and certifications 60 and 30 days before expiration. PPGP/CHPPGP assumes no responsibility if a license or certification expires.
- In Missouri, APRNs must:
  - fax their renewed certification to the Missouri State Board of Nursing
    - The fax number is: **573-522-2143**
  - save the fax confirmation receipt.
  - After sending the fax, APRNs will telephone the Missouri State Board of Nursing to confirm the Board received their certification renewal.
    - The phone number to call is: **573.751.0681**
  - The APRN will document this phone call and save the documentation because the Missouri State Board of Nursing has denied receiving several faxed certifications in 2015 and 2016.
- The Director of CQRM will search on line to make sure the appropriate licensing entity posted the renewal.
- The Director of CQRM will notify the VP of Health Clinical Services and the Revenue Cycle Director if a license or certification expires (Medicaid may not reimburse care provided by an LIP with expired credentials).

Privileging Policy

It is the policy of PPGP/CHPPGP that only those health professionals who by state law, education and training are qualified to perform a particular clinical function are allowed to do so. Specialized services must only be provided by clinicians who are trained and demonstrate proficiency in those specific areas. Examples include, but are not limited to, performing ultrasound, colposcopy and Norplant and IUC insertions and removals. Determining the competency of each clinician is the responsibility of the Medical Director for physicians or Lead Clinician for APRNs and PAs.

Privileging Process

Newly Hired Practitioner – all newly hired physicians and APRN/PAs must undergo a period of supervised practice called proctoring. Proctoring is required regardless of pay status (employed, contracted, volunteer), length of experience prior to joining, or length of service (ex. employed 5 years and begins providing colposcopies). Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and is delegated to the Lead Clinician for PA/APRNs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form located in the PPFA Clinician Performance Monitoring Toolkit.

Practitioners Seeking Additional Privileges will be proctored by a practitioner who is privileged to perform the procedure. Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and Lead Clinician for APRN/PAs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form, located in the PPFA Clinician Performance Monitoring Toolkit.

Ongoing Professional Practice Evaluation Policy

It is PPGP/CHPPGP's policy to conduct ongoing professional practice evaluation (OPPE) at least annually to ensure clinicians are providing and documenting care consistent with the MS&Gs and the PPGP/CHPPGP mission. If OPPE reveals adverse data, the Medical Director will develop a performance improvement plan that may include altering the provider's privileges, additional proctoring, education, discipline, or termination, in order to ensure patient safety.

Ongoing Professional Practice Evaluation Procedure

PA/APRN OPPE

The Medical Director is responsible for APRN/PA OPPE but may delegate the review to the Lead Clinician. The Lead Clinician will report all findings to the Medical Director for final determination of competency. Competency will be evaluated within 3 months of hire and annually at a minimum.

Methods of review include:

- Chart Audit: The Lead Clinician will audit at least 10 patient charts for the PA/APRN annually and as needed.
- Observation: The Lead Clinician will observe the APRN/PA during orientation and annually. Areas of observation will include history taking, patient education, physical assessment, infection control, patient management, and charting.
- Microscopy: The Lead Clinician will assess Vaginal Wet Mount Microscopy accuracy semi-annually and will evaluate competency annually. At the annual evaluation, microscopy skills will be observed. In addition, at least 5 slides will be reviewed by the APRN/PA and the Lead Clinician with an expectation of 80% agreement. Semi-annually, the APRN/PA will be tested on reading at least 4 microscope photos with an expectation of 100% accuracy.
- Training and Meetings: PA/APRNs are expected to participate in PPGP/CHPPGP Leadership Team Meetings and training opportunities.
- Referral Protocol: The Lead Clinician will review APRN/PA compliance with the referral protocol via annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.
- Pap Protocol: PA/APRNs will be reviewed for compliance with the abnormal pap protocol. Review will be by annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.

Lead Clinician OPPE

The Medical Director will perform the Lead Clinician's OPPE based on the above review methods. Additionally, the Lead Clinician will be evaluated on her/his oversight of the provision of clinic medical services, including APRN/PAs, medical assistants, RNs, LPNs, and student PA/APRNs. The Lead Clinician will be evaluated on how well she/he works with the clinic managers to communicate any changes in medical care and protocols to clinic staff.

Physician OPPE

The Medical Director is responsible for performing physician OPPE. Competency will be evaluated within 3 months of hire and annually. The Medical Director will employ the following methods of review:

- Observation: Areas of review will include surgical technique, communication with staff, professional rapport with patients and infection control.
- Chart Audit: Patient care chart audits of at least 10 charts will be performed annually and as needed to assure compliance with the MS&Gs. All areas of service the physician provides will be included. Areas of review will include consent, history, lab, assessment, plan, and referral.
- Risk Management: Physician complication statistics will be compiled annually and reviewed for trends by the Medical Director, staff physicians, Director of CHPPGP, and Director of Quality and Risk Management. An annual complication rate will be included in the annual physician review with an expectation of less than 2% complication rate.
- Training and Meetings: Physician is expected to participate in CME meetings and training opportunities.

Medical Director OPPE

The Medical Director's OPPE will be performed by an outside physician consultant. Additionally, the Medical Director will be evaluated on how well he/she fulfills the Medical Director job description.

Ultrasound Quality Improvement Program OPPE

PPGP has an ongoing ultrasound quality improvement program for all staff that performs ultrasounds that includes:

- Initial training
- Proctoring
- Privileging
- Monitoring
- Ongoing proficiency

All staff who perform ultrasounds for abortion care will demonstrate competence initially by completing the Ultrasound Privileging form (located in the PPFP Clinician Performance Monitoring Toolkit (2013), watching the CAL ultrasound videos, proctoring, an annual observation and annual chart review of 10 random chart by the Lead Clinician.

Quality/Peer Review Policy

Where OPPE occurs annually and examine the provider's competence, the Quality / Peer Review Committee (QPRC) meets quarterly and examines unwanted clinical outcomes for trends and opportunities for improvement. It is the policy of PPGP/CHPPGP for the QPRC to review all unwanted patient outcomes. The process is protected under state and federal physician peer review, quality improvement, and patient safety statutes. Each participant should sign a confidentiality agreement and not discuss cases outside of the QPRC meeting to maintain protection from legal discovery.

As an ambulatory surgery center licensed by the Kansas Department of Health and Environment, the PPGP/CHPPGP is required to have a written risk management plan that is approved by the Board of Directors and submitted to KDHE annually (K.S.A. 65-492 and K.A.R. 28-52-1 through 28-52-4). The Risk Management Plan requires establishing a quarterly Peer Review meeting with at least 2 physicians. If there are fewer than 2 physicians on the CHPPGP ASC Medical Staff, KDHE requires the Peer Review Committee to procure an outside physician consultant.

Missouri also requires ambulatory surgery centers to have a Risk Management Plan. These plans are located: Q drive > Public Departments > Clinical Services > ALL Manuals> shortcut.

QPRC Procedure

- The QPRC is composed of the Medical Director and at least 1 additional physician.
- APRN/PAs are typically invited to attend the meetings and contribute.
- The CHPPGP Surgical Nurse Managers/CHPPGP Ambulatory Surgery Center Risk Managers attends and presents cases.
- The Director of CQRM drafts the agenda and records minutes.
- The QPRC members review the care provided and ask:
    - Was the complication or unwanted outcome known to be associated with the procedure
    - Was the complication recognized in a timely manner
    - Was the complication treated appropriately
    - Was the standard of care met
    - Was the complication part of a larger trend, and
    - Is there an opportunity for providers to improve the quality and safety of patient care?

The QPRC functions under the constructs of the Just Culture algorithm where the main focus is on learning and improving safety.

For CHPPGP cases, if the physicians find that the provider failed to meet the standard of care and the patient was harmed or was likely to have been harmed, the QPRC is required to report the case to KDHE. It is the policy of CHPPGP not to report cases to KDHE that did not occur in the ambulatory surgery center.

The state of Missouri requires abortion facilities in the state to report all complications. This requirement is described in the Missouri Risk Management Plan.

The Medical Director or Lead Clinician will assist practitioners who may require performance improvement activities.

The Medical Director or delegate will contact legal counsel where there may be an incident that is reportable to the state licensing agency or National Practitioner Data Bank.

Medical Director and Board of Director Review Schedule

Board of Directors appoint new CHPPGP Medical Staff Members for KS & MO	Review at Board meeting after completion of orientation, credentialing & privileging	Kansas Ambulatory Surgery Center Regulation 28-34-53
Board of Directors approve CHPPGP Risk Management Plan for KS & MO	Annually	Kansas Ambulatory Surgery Center Regulation 28-34-50(b)(1)
Medical Director & Lead Clinician approve MS&Gs	Annually	Required by PPFA as stated in Administrative chapter 1.

Resources

- Comprehensive Health of Planned Parenthood Great Plains Ambulatory Surgery Center Quality and Risk Management Plan (including pharmacy, lab and infection prevention)
- ARMS Credentials Verification: A Reference Guide for Planned Parenthood Affiliates
- PPFP Medical Director Orientation Manual (2014)
- PPFP Clinician Performance Monitoring Toolkit (2013)
- Kansas ASC Risk Management Planned Parenthood of Kansas and Mid-Missouri
- Missouri Abortion Facility Risk Management Plan
- Forms:
    - Clinician Skills Checklist: Proctoring Form
    - Clinical Privilege Form
    - Annual Clinician Performance Evaluation
    - Chart Review Form
    - OSHA evaluation

EXHIBIT 3

LABORATORY SERVICES AGREEMENT

THIS AGREEMENT made this 2nd day of May 2017, by and between Comprehensive Health of Planned Parenthood Great Plains, ("CLIENT") and Boyce & Bynum Pathology Laboratories, P.C. ("LABORATORY").

WHEREAS, LABORATORY is engaged in the business of providing reference clinical laboratory services (the "Services"); and

WHEREAS, CLIENT desires to contract with LABORATORY to provide reference clinical laboratory services for CLIENT, and LABORATORY desires to provide the Services described herein.

IT IS THEREFORE AGREED AS FOLLOWS:

1. TERM AND TERMINATION

This Agreement shall become effective on the date set forth above and shall continue in effect until terminated by either party. This Agreement shall have an initial term of one (1) year ("Initial Term") and shall be automatically renewed for additional periods of one (1) year ("Renewal Term") at the end of the Initial Term or any Renewal Term, unless previously terminated by either party.

This Agreement may be terminated by either party, with or without cause, at any time, by giving the other party thirty (30) days prior written notice to the address set forth in Section 9.

2. TESTING SERVICES

LABORATORY agrees to perform such Services for CLIENT as may be requested by CLIENT, if available, during the term of this Agreement. The Services shall include those tests listed in LABORATORY's current Directory of Services, as the same may be modified from time to time by LABORATORY and such additional services as the parties may agree to in writing.

3. ADDITIONAL SERVICES

A. SPECIMEN PICK UP AND REPORT DELIVERY

LABORATORY will provide a reference specimen pick up and report delivery service to CLIENT on a daily basis Monday through Friday and Saturday as requested. LABORATORY shall make reasonable efforts to deliver or transmit results of a routine nature (general routine chemistries) to CLIENT within 24 hours of the time the specimen is received by LABORATORY's testing facility. LABORATORY shall make reasonable efforts to deliver or transmit results of tests performed on specimens of a special nature (special chemistries, tissues, etc.) to CLIENT within the times set forth in LABORATORY's then current turn-around-time schedule. LABORATORY shall report panic or critical values performed at LABORATORY facilities in a manner consistent with LABORATORY's standard policies and procedures. CLIENT hereby represents and warrants that it has reviewed such policies and procedures and further acknowledges that it understands and agrees with LABORATORY policies and procedures.

B. CONSULTATION

LABORATORY staff shall be available to consult with CLIENT by telephone during normal LABORATORY working hours to discuss LABORATORY's procedures and to provide the status of test results.

4. FEES

CLIENT agrees to pay, to the extent responsible for payment, for the Services provided under this Agreement the fees set forth in Exhibit A. CLIENT shall pay the greater of the fees listed in Exhibit A or the charges to LABORATORY for reference testing performed by a laboratory not owned by or affiliated with LABORATORY. In no event shall the fees paid to LABORATORY for reference testing performed by a laboratory not owned or affiliated with LABORATORY exceed agreed upon rate structure. After the Initial Term of this Agreement, CLIENT and LABORATORY agree that fees shall either increase on the renewal date hereof or with LABORATORY's general annual fee increase of which CLIENT shall receive thirty (30) days written notice. In no event shall a fee increase enacted on the renewal date exceed the LABORATORY'S general annual fee increase without the written consent of the CLIENT. CLIENT and LABORATORY acknowledge and agree that fees shall not be adjusted more frequently than once a year.

Notwithstanding the foregoing, CLIENT acknowledges that LABORATORY may develop and/or provide new technologies and/or new methodologies during the term of this Agreement. LABORATORY shall notify CLIENT when such technologies and/or methodologies are available and the fee associated with such technologies and/or methodologies. If, during the term of this Agreement, any nationally recognized professional medical association makes recommendations that establish or change a standard of care for testing, the parties will work in good faith to agree on an appropriate rate of payment for testing affected by the new or modified standard of care on a fee for service basis. If the parties cannot reach agreement, LABORATORY shall have the right to terminate this Agreement by giving thirty (30) days written notice to CLIENT.

5. BILLING

CLIENT shall indicate the entity responsible for payment of Services rendered on the requisition submitted to LABORATORY. CLIENT shall submit to LABORATORY 3rd party payment information for all patients with 3rd party coverage.

If CLIENT indicates that CLIENT is responsible for payment, LABORATORY will submit to CLIENT a monthly statement of Services rendered to CLIENT by LABORATORY for the prior month and CLIENT agrees to remit payment to LABORATORY for Services. Payment for Services is due thirty (30) days after the date of invoice. Failure to remit payment within said time may result, among other remedies available to LABORATORY, in discontinuation of Services. Nothing in the foregoing provision shall serve to waive any rights or remedies available to LABORATORY with respect to its providing Services to CLIENT. If LABORATORY is compelled to bring suit to collect amounts due hereunder LABORATORY shall be entitled to recover from CLIENT interest on amounts due in accordance with Missouri Revised Statute 408.040, reasonable attorney's fees and costs of suit incurred in connection with such action.

If CLIENT indicates that a third party is responsible for payment, LABORATORY, in accordance with legal and regulatory requirements, agrees to bill the patient or other responsible party, including Medicare, Medicaid and insurance companies, for Services performed under this Agreement. CLIENT agrees to promptly provide LABORATORY with all necessary information to accomplish the billing and collection of amounts due, including required diagnosis information. If LABORATORY is unable to obtain payment from any third party due to CLIENT's failure to provide the information required by this Agreement, or as a result of CLIENT's failure to follow applicable rules or regulations, CLIENT agrees to pay LABORATORY for all such Services.

6. ACCREDITATION OF TESTING SITES

The Services performed hereunder shall be performed at testing facilities to be selected by LABORATORY. LABORATORY's facilities are and shall remain duly licensed clinical laboratories under applicable federal, state and local law. Reasonable documentation of such credentials shall be provided upon written request.

7. CHANGE IN LAW OR REGULATION

The terms of this Agreement are intended to be in compliance with all federal, state and local statutes, regulations and ordinances applicable on the date the Agreement takes effect including but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Deficit Reduction Act of 2005 ("DRA"), and applicable State False Claims Acts ("SFCA"). The parties agree to execute amendments as may be necessary for the continuing compliance with the aforementioned Acts, as additional regulations are promulgated or become final and effective. Should either party reasonably conclude that any portion of this Agreement is or may be in violation of such requirements or subsequent enactments by federal, state or local authorities, or if any such change or proposed change would materially alter the amount or method of compensating LABORATORY for Services performed for CLIENT or for any other party under this Agreement, or would materially increase the cost of LABORATORY's performance hereunder, the parties agree to negotiate written modifications to this Agreement as may be necessary to establish compliance with such authorities or to reflect applicable changes.

8. NON-ASSIGNABILITY

This Agreement may not be assigned by either party without the written consent of the other party which consent shall not be unreasonably withheld or delayed.

9. NOTICES

Any notice required to be given pursuant to the terms and provisions hereof shall be in writing and shall be sent by certified or registered mail to LABORATORY at:

Boyce & Bynum Pathology Laboratories, P.C.
200 Portland St
Columbia, MO 65201
Attention: Compliance

and to CLIENT at:

Regional Director of Health Center Operations
Comprehensive Health of Planned Parenthood Great Plains
4401 W 109th St., Ste 200
Overland Park, KS 66211
Attention: Vicki Casey

10. INDEPENDENT RELATIONSHIP

None of the provisions of this Agreement are intended to create, nor shall be deemed or construed to create, any relationship between CLIENT and LABORATORY other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Agreement. Neither of the parties hereto, nor any of their respective employees shall be construed to be the agent, employer or representative of the other.

11. FORCE MAJEURE

Neither LABORATORY nor CLIENT shall be liable for any claims or damages and shall be excused for such claims, damages, failures and delays in the performance of its obligations under this Agreement due to any act or cause beyond the reasonable control and without the fault of LABORATORY or CLIENT including, without limitation, acts of God such as fire, flood, tornado, earthquake; acts of government (i.e., civil injunctions or enacted statutes and regulations); or acts or events caused by third parties such as riot, strike, power outage or explosion; or the inability due to any of the aforementioned causes to obtain necessary labor or materials.

12. WARRANTY

A. CLIENT WARRANTS TO LABORATORY THAT NEITHER CLIENT NOR ANY OF ITS EMPLOYEES OR OWNERS HAVE BEEN DEBARRED, SUSPENDED, DECLARED INELIGIBLE OR EXCLUDED FROM MEDICARE, MEDICAID OR ANY OTHER FEDERAL OR STATE GOVERNMENT HEALTHCARE PROGRAM.

B. LABORATORY WARRANTS TO CLIENT THAT NEITHER LABORATORY NOR ANY OF ITS EMPLOYEES OR OWNERS HAVE BEEN DEBARRED, SUSPENDED, DECLARED INELIGIBLE OR EXCLUDED FROM MEDICARE, MEDICAID OR ANY OTHER FEDERAL OR STATE GOVERNMENT HEALTHCARE PROGRAM.

C. LABORATORY WARRANTS TO CLIENT THAT ALL SERVICES PROVIDED HEREUNDER SHALL BE IN ACCORDANCE WITH ESTABLISHED AND RECOGNIZED CLINICAL LABORATORY TESTING PROCEDURES AND WITH REASONABLE CARE IN ACCORDANCE WITH APPLICABLE FEDERAL, STATE AND LOCAL LAWS AND REGULATIONS.

D. NO OTHER WARRANTIES ARE MADE BY LABORATORY.

E. NO OTHER WARRANTIES ARE MADE BY CLIENT.

F. IN NO EVENT SHALL LABORATORY OR PPSLRSWMO BE RESPONSIBLE FOR ANY PUNITIVE DAMAGES OR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, OR SPECIAL DAMAGES OF CLIENT OR OF ANY THIRD PARTY.

13. BENEFIT

This Agreement is intended to inure only to the benefit of LABORATORY and CLIENT. This Agreement is not intended to create, nor shall be deemed or construed to create, any rights in any third parties.

14. NONDISCRIMINATION

All Services provided by LABORATORY hereunder shall be in compliance with all applicable Federal and State laws, regulations and ordinances prohibiting discrimination on the basis of race, color, religion, sex,

national origin, handicap, veteran status or any other protected class.

15. HEADINGS

The headings in this Agreement are for convenience and reference only and are not intended to, and shall not, define or limit the scope of the provisions to which they relate.

16. ENFORCEABILITY/SEVERANCE CLAUSE

The invalidity or unenforceability of any term or provisions of this Agreement in any jurisdiction shall not affect the validity or enforceability of any of the other terms or provisions in that jurisdiction or of the entire Agreement in any other jurisdiction. If any provision is held invalid by a court of competent jurisdiction, such shall be severed and the Agreement shall be interpreted as though the severed provision had not existed.

17. WAIVER

No course of dealing between the parties or any delay on the part of either party in exercising any rights they may have under this Agreement shall operate as a waiver of any of the rights of the other party. No express waiver shall affect any condition, covenant, rule, regulation, right or remedy other than the one specified in such waiver and only for the time and in the manner specifically stated.

18. ACCESS TO BOOKS AND RECORDS

If the Services to be provided by LABORATORY hereunder are subject to the disclosure requirements of 42 U.S.C. 1395x (v) (1) (I), LABORATORY shall until expiration of ten (10) years make available, upon written request of the Secretary of Health and Human Services, or upon request to the Comptroller General, or any of their duly authorized representatives, a copy of this Agreement and the books, documents and records of LABORATORY that are necessary to certify the nature and extent of the costs incurred under this Agreement through a subcontractor with a value or cost of $10,000.00 or more over a twelve (12) month period. In addition, with respect to any applicable subcontract, such subcontract shall contain a clause to the effect that, should the subcontractor be deemed a related organization, until the expiration of six (6) years after the furnishing of services pursuant to such subcontract, the subcontractor shall make available upon written request of the Secretary of Health and Human Services, or upon request to the Comptroller General, or any of their duly authorized representatives, a copy of the subcontract, and the books, documents and records of such third party that are necessary to verify the nature and extent of the costs incurred under this Agreement. Should LABORATORY and/or a subcontract receive such a request, CLIENT shall be notified in writing of the request within five (5) days.

During the term of this Agreement, upon reasonable prior written request and during normal business hours, LABORATORY shall allow CLIENT reasonable access to LABORATORY records concerning the Services provided hereunder. CLIENT warrants and represents that it has obtained any necessary written consent from CLIENT patients for the release of such records. Such consent shall satisfy all applicable laws and regulations including but not limited to the privacy regulations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

19. MODIFICATION

This Agreement may only be modified in a writing signed by authorized representatives of each party.

20. ENTIRE AGREEMENT

This Agreement constitutes the entire understanding between the parties hereto concerning the subject matter herein and is a complete statement of the terms thereof and shall supersede all previous understandings between the parties, whether oral or written with respect to the subject matter herein. The parties shall not be bound by any representation made by either party or agent of either party that is not set forth in this Agreement. Any applicable provisions required by federal, state, or local law are hereby incorporated by reference.

21. GOVERNING LAW

This Agreement shall be construed under the laws of the State of Missouri.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in their names as their official acts by their respective representatives, each of whom is duly authorized to execute the same.

LABORATORY:
Boyce & Bynum Pathology Laboratories, P.C.

By: _____

Print Name: Richard Cotten

Date: 05/09/2017

CLIENT:

Comprehensive Health of Planned Parenthood Great Plains

By: _____

Print Name: Aaron Samulcek

Date: 5/9/17

Americans United for Life

EXHIBIT A
FEES

For the Services ordered by CLIENT and performed by LABORATORY that are not set forth attached, CLIENT agrees to pay the fees set forth in LABORATORY's current Professional Fee Schedule labeled Base 14 as modified from time to time by LABORATORY.

Americans United for Life

EXHIBIT 4

Americans United for Life

AUTOCLAVE LOG for Month Dec 2016

Clinic: Columbia

Biomedical company: BESS **Last Calibration Date:** 1

Date of Monthly Infection Prevention Maintenance (Clean, drain & replace water): 12/8/16

Dates of weekly spore testing & results:

date of week 1 12/6/16 (pass) / fail (circle one)

date of week 2 12/12/16 (pass) / fail (circle one)

date of week 3 12/22/17 (pass) / fail (circle one)

date of week 4 _____ pass / fail (circle one)

*Autoclave not working Dec 4th Week

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
12/6/16	1	Curved Forcep	1	FP	Pass	Pass	10:50AM	260°F	KPR
		Speculum	9	FP	Pass	Pass	10:50AM	260°F	KPR
12/7/16	1	Curved Forcep	2	FP	Pass	Pass	9:13AM	260°F	KPR
same time 12/7/16	1	Strait Forcep	4	FP	Pass	Pass	9:13AM	260°F	KPR
12/8/16	1	Speculum	10	FP	Pass	Pass	9:13AM	260°F	KPR
12/9/16	1	Curved Forcep	2	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Strait Forcep	2	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Ring Forcep	1	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	UVB Pack	2	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Speculums	4	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Long Strait Forcep	1	FP	Pass	Pass	9:43AM	260°F	KPR
12/12/16	1	Strait Long Forcep	1	FP	Pass	Pass	9:18AM	260°F	KPR

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
12/12/16	1	speculum	3	FP	Pass	Pass	9:18am	260°F	KPRW
12/16/16	1	IUD Pack	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	small straight forcep	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	small curved forcep	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	Colp Biopsy Punch tool	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	Colp Straight ends	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/22/16	1	Specula	15	FP	pass	pass	12:50pm	260°F	MWelmaker
12/22/16		1 Sound	1	FP	pass	pass	12:50pm	260°F	MWelmaker
12/22/16		Curved straight forcep	1 each	FP	pass	pass	12:50pm	260°F	MWelmaker
1/3/17		Specula	8	FP	pass	pass	10:30am	260°F	MWelmaker
1/25/16	1	Specula		FP	Pass	Pass	9:30am	260°F	
1/25/16	1	Forceps		FP	Pass	Pass	9:30am	260°F	
1/25/17		Speculum		FP	Pass	Pass	5:30pm	260°F	
1/25/17		Speculum		FP	Pass	Pass	5:30pm	260°F	

AUTOCLAVE LOG for Month March

Clinic: Columbia

Biomedical company: BESS **Last Calibration Date:** QRM √ list

Date of Monthly Infection Prevention Maintenance (Clean, drain & replace water): 3/30/17

Dates of weekly spore testing & results:

date of week 1_____ **pass / fail (circle one)**

date of week 2_____ **pass / fail (circle one)**

date of week 3_____ **pass / fail (circle one)**

date of week 4_____ **pass / fail (circle one)**

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
3/9/17		Scan - 2 IUD packs	12	FP		pass	2:04	260°	
3/10/17		Speculum		FP		pass	9:03	260°	
"		Scissors	2	FP		pass	9:03	260°	
"		forcep Ring	1	FP		pass	9:03	260°	
3/10/17		2 IUD packs 1 scissors	3	FP		pass	11:4	260°	
3/10/17		4 alligator clamps	4	FP		pass	1:49p	260°	
"		2 Ring forcep	2	FP		pass	1:49p	260°	
"		IUD pack	1	FP		pass	1:49p	260°	
"		Alligator clamps	3	FP		pass	3:35p	260°	
"		tenaculum	1	FP		pass	"	260°	
"		Speculums	10	FP		pass	"	260°	
3/22/17		10 speculums	10	FP		Pass	9:42	260°	

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
3/23/17		IUC Pack	2	FP		pass	9:42	260°	
"		Ring forceps	2	FP		pass	9:42	260°	
"		Ring forcep	1	FP		pass	1:31p	260°	
"		sound	1	FP		pass	1:31p	260°	
"		Tenaculum IUC pack	1	FP		pass	1:31p	260°	
3/22		~~tenaculum~~	~~1~~			~~pass~~			
3/22		Specculums	9	FP		pass	1:31p	260°	
3/24/17		tenaculum	1	FP		Pass	2:03p	260°	
"		specculums	10	FP		pass	2:03p	260°	
"		~~Scissor~~ sisscors	4	FP		Pass	2:03p	260°	
3/24/17		specculums	13	FP		Pass	1:19p	260°	
"		IUC pack	1	FP		pass	1:19p	260°	
"		Sisscors	1	FP		pass	1:19p	260°	
3/24/17		Alligator forcep	1	FP		pass	1:19p	260°	

AUTOCLAVE LOG for Month March/April 2017

Clinic: Columbia

Biomedical company: BESS **Last Calibration Date:** APRN V list

Date of Monthly Infection Prevention Maintenance (Clean, drain & replace water): _____

Dates of weekly spore testing & results:

date of week 1_____ **pass / fail (circle one)**

date of week 2_____ **pass / fail (circle one)**

date of week 3_____ **pass / fail (circle one)**

date of week 4_____ **pass / fail (circle one)**

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
3/31/17		IUC Pack	1	FP		Pass	9:54A	260°	
1		tenaculum	1	FP		Pass	9:54A	260°	
"		Specula ums		FP		pass	9:54A	260°	
4/6/17		IUC Pack	2	FP		pass	9:56A	260°	
"		Scissors	1	FP		P	9:56A	260°	
4/6/17		forceps Misquite	1	FP		P	9:56A	260°	
"		Specula ums	12	FP		P	9:56A	260°	
4/14/17		Ring forceps	4	FP		P	12:20	260°	
4/14/17		Misquite forceps	1	FP		P	12:20	260°	
4/14/17		IUC pack	1	FP		P	12:20	260°	
"		Specula ums	10	FP		P	12:20	260°	

HENRY SCHEIN®

135 Duryea Road, Melville, NY 11747
Questions: 1-800-472-4346

INVOICE

0100002214493406988141100000000002469404131174

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

SHIP TO/SOLD TO:
PP-Columbia Center MD
711 N Providence Rd
Orrin Moore
Columbia,MO 65203-4357

BILL TO:
Planned Parenthood Great Plains MD
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

BILL TO	SHIP TO	INVOICE AMOUNT
2214493	3329559	246.94

INVOICE#	INVOICE DATE
40698814	4/13/17

CUSTOMER PO#
COL-AB-04122017

ORDER#	ORDER DATE	DUE DATE
51118304	04/12/17	05/13/17

D&B#:01-243-0880
WHSE DEA# RH0162494 Fed ID: 11-3136595

LINE NO	ITEM CODE	UNIT SIZE	DESCRIPTION & STRENGTH	QUANTITY ORDERED	QUANTITY SHIPPED	ITEM STATUS	UNIT PRICE	EXTENSION	BOX NO	REM
			This order has been processed by our MIDWEST D.C. 5315 WEST 74TH STREET INDIANAPOLIS,IN 46268							
1	600-9638	1/BX	SOAKING CUP F/TRANSDUCER, ENDOCAV ** SPECIAL CONTRACT PRICE ** CASE GOOD ITEM, MAY BE SHIPPED SEPARATELY.	1	1	C T	96.04	96.04		
2	763-0012	EA	REVITAL-OX RESERT XL HLD 4LITER .GO TO YOUR ONLINE ACCOUNT TO RETRIEVE THIS MSDS/SDS, 105N508 - IF YOU CAN'T ACCESS ONLINE OPTIONS, CALL 1-800-472-4346. ** SPECIAL CONTRACT PRICE **	1	1	*T	41.68	41.68		
3	124-4695	120/CA	STRIP TEST RVTL-OX RESERT ** SPECIAL CONTRACT PRICE **	1	1	T	93.96	93.96		

INCLUDED IN THE BELOW FREIGHT CHARGE IS A FUEL/HANDLING SURCHARGE. FOR THE CURRENT TERMS OF SALE GOTO HTTP://WWW.HENRYSCHEIN.COM/US-EN/MEDICAL/LEGALTERMS.ASPX
PLEASE REFER TO BACK OF PAPERWORK FOR DISCLOSURES/TERMS OF SALE

PLEASE NOTE THAT LATE PAYMENTS ARE SUBJECT TO A 1.5 % MONTHLY FINANCE CHARGE

MERCHANDISE TOTAL	231.68
SALES TAX	[illegible]

BILL TO	SHIP TO	INVOICE#	INVOICE AMOUNT
2214493	3329559	40698814	246.94
ORDER#	ORDER DATE	INVOICE DATE	# OF BOXES
51118304	04/12/17	4/13/17	2
CUSTOMER PO#			PAGE#
COL-AB-04122017			1

ITEM STATUS KEY
B - Backordered; Item will follow
D - Discontinued; Item no longer available
F - Special offer
M - Manufacturer will ship Item directly to you
P - Prescription Drug; Return Authorization Required
R - Refrigerated Item; May be shipped separately
$ - Special Schein Pricing
T - Taxable Item
U - Temporarily unavailable; please reorder
* - Item has MSDS

REM KEY
S - Special Kit
N - No Charge

Continued on Next Page .....

HENRY SCHEIN®

135 Duryea Road, Melville, NY 11747
Questions: 1-800-472-4346

INVOICE

0100002214493406988141100000000002469404131174

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

SHIP TO/SOLD TO:
PP-Columbia Center MD
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Orrin Moore
Columbia,MO 65203-4357

BILL TO:
Planned Parenthood Great Plains MD
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

BILL TO	SHIP TO	INVOICE AMOUNT
2214493	3329559	246.94

INVOICE#	INVOICE DATE
40698814	4/13/17

CUSTOMER PO#
COL-AB-04122017

Please detach here and mail the above with your payment

ORDER#	ORDER DATE	DUE DATE
51118304	04/12/17	05/13/17

D&B#:01-243-0880
WHSE DEA# RH0162494 Fed ID: 11-3136595

LINE NO	ITEM CODE	UNIT SIZE	DESCRIPTION & STRENGTH	QUANTITY ORDERED	QUANTITY SHIPPED	ITEM STATUS	UNIT PRICE	EXTENSION	BOX NO	REM
						FREIGHT	CHARGES	5.25		
						Invoice Date +	30 days	246.94		

Please remit payments only to the following address:
Henry Schein, Inc.
Dept CH 10241
Palatine, IL 60055-0241

BILL TO	SHIP TO	INVOICE#	INVOICE AMOUNT
2214493	3329559	40698814	246.94
ORDER#	ORDER DATE	INVOICE DATE	# OF BOXES
51118304	04/12/17	4/13/17	2
CUSTOMER PO#			PAGE#
COL-AB-04122017			2

ITEM STATUS KEY
B - Backordered; Item will follow
D - Discontinued; Item no longer available
F - Special offer
M - Manufacturer will ship Item directly to you
P - Prescription Drug; Return Authorization Required
R - Refrigerated Item; May be shipped separately
$ - Special Schein Pricing
T - Taxable Item
U - Temporarily unavailable; please reorder
* - Item has MSDS

REM KEY
C - No charge

Planned Parenthood®
Care. No matter what.

Planned Parenthood Great Plains

Policy: CLEANING THE ULTRASOUND PROBE AND CARE OF THE ULTRASOUND MACHINE

Originator: Kristin Metcalf-Wilson DNP, WHNP-BC

Approval Date: 04/01/2017

Policy:

Ultrasound machines constitute a significant resource investment for the agency. Although care must be taken with all aspects of the machine, the probes are especially delicate. Be sure to refer to the owner's manual/manufacturer's recommendations provided with the machine being used in the center.

The level of disinfection needed in between patients is determined by the route of scanning and the type of tissue contact. Transvaginal ultrasound constitutes endocavity scanning with mucous membrane contact and thus requires high level disinfection of the probe between patients. Although the use of probe covers may minimize probe contamination, the failure rate is surprisingly high and their use does not remove the need for high level disinfection. Abdominal scanning over intact skin poses little contamination risk, making a lower level of disinfection acceptable.

Process in the Clinics:

Starting the day

- Inspect all cords and probes for possible defects that may pose a safety hazard to the operator or patients.
- Ensure that any cords are tucked out of the way and uncoiled. Rolling over, stepping on or continuous tangling of the probe cords may damage the wires contained within the cords, causing imaging problems.
- Ensure proper supplies are available: ultrasound gel, non-latex sheaths and/or condoms for use with the vaginal probe, drape sheets, mild soap, cleaning agent(s) and soaking container, indicator strips and log for results, 2x4 labels, soft cloths, Resert XL HLD solution, and a timer.

General cleaning considerations

- All probes should be disconnected from the machine before they are cleaned to minimize safety hazards (i.e. shock to the operator, water damage to the machine).
- Although paper towels may be used to gently remove a soiled sheath, they should not routinely be used in any other part of the cleaning process. Paper towels are like sandpaper to the probe's delicate membrane surface.

- A soft cotton pile or microfiber cloth/towel should be used in any of the cleaning routines that follow. Although there are some disposable disinfecting wipes on the market, they do not provide the high level disinfection needed for the vaginal probe.
- A new cloth/towel is needed for every step in the process, so one should have access to at least three cloths per every scan. The microfiber towels (available at Costco or most automotive parts stores) can easily be cut into smaller squares (4 per towel) without fraying of the material.
- Launder cloths/towels according state guidelines and in a manner that maintains their softness. Towels that have lost their softness should be discarded as they may harm the probe membrane. Microfiber towels should not be exposed to fabric softener as it diminishes their absorptive abilities.

Resert XL HLD Solution for high level disinfection

Cleaning agents vary in the length of time needed to achieve high level disinfection, cost, and associated materials needed for the safe use of the cleaning agent. In an effort to provide high level disinfection in the least complicated manner and the shortest possible period of time, Resert is used to disinfect the probe.

Resert XL HLD is a ready to use, high level disinfecting solution. Unlike other high level disinfecting agents, it is virtually odorless, requiring no special ventilation, non-staining, and does not require special precautions (dilution or deactivation) for disposal.

Once poured into the soaking chamber, Resert XL HLD solution is good for up to 21 days of reuse provided that the minimum recommended concentration (MRC) of 1.5% is present, as verified by the approved indicator strips. A log of indicator results should be maintained.

The original open date should be recorded on the Resert XL HLD solution bottle using labels. The manufacturer's information indicates that the solution is good in the original container until the expiration date listed on the container. The soaking chamber should also have a center-applied label that lists the date the solution was poured into it, solution expiration date and the anticipated 21 day end of life date. At the start of every day, the solution must be tested with a Verify Chemical Monitoring Strip for Resert Solutions. Record the results of the test in the Resert Log. If the solution fails the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin. The solution should be covered at the end of every day. Please note that the color of the solution may change to light amber over time. This is not an indication of a problem as long as the MRC is verifiable.

Steris, maker of Resert XL HLD, suggests the following procedure for the using Verify Chemical Monitoring Strip for Resert Solutions:

- Ensure that the bottle of indicator strips is labeled with an open date. The strips expire 90 days from the open date or on the listed expiration date, whichever date comes first.
- Remove an indicator strip from the bottle. Dip the indicator pad into the soaking solution for 2 seconds, blot any excess by touching the edge of the pad to a paper towel, and then lay flat with the indicator pad facing up for 90 seconds, using a timer to monitor. Compare strip to color reference on the bottle.
- At the end of 90 seconds, read and record the result in the appropriate log. A "pass" is indicated by a color change from yellow to black. A "fail" is indicated by any blue or yellow remaining on the pad after 90 seconds.

- If the solution "fails" the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin.
- Controls should be run upon opening any new bottle of indicator strips.
    - For the positive control, dispense approximately 30mL of Resert XL HLD solution from an unopened bottle into a clean container. Run three test strips as per usual routine. All three strips must "pass."
    - For the negative control, dispense 15mL of Resert XL HLD solution from an unopened bottle into a clean plastic bottle, add 15mL of tap water to the bottle, and gently mix. Run three test strips as per usual routine. All three test strips must "fail."
    - If all six strips result as expected, the new bottle of Verify Chemical Monitoring Strip for Resert Solution may be used until the listed expiration date, whichever comes first. Be sure to record the open and controls run date on the bottle itself and in the log.
- Check state and local disposal regulations. Any expired or "failing" solution may be disposed of by flushing down the drain with water. The original container should be triple rinsed with water before tossing. Consult the MSDS for first aid measures. The indicator strips contain dye that may stain once activated but otherwise require no special precautions.

Cleaning of the vaginal probe

- Begin the day by testing the soaking solution to ensure that the MRC is met and verify that it is within the 21 day reuse range. Document results in the appropriate log.
- After scanning, unplug the probe from the machine and set the connector (plug) in the holder on the mounting kit that houses the soaking cup.
- Remove the contaminated probe cover with a paper towel and discard. Rinse the probe under water to remove any excess gel.
- Gently and thoroughly clean the probe using mild dish soap and a soft cloth, then rinse with running water, and dry with a clean soft cloth. Drying is important because it prevents progressive dilution of the soaking solution.
- Gently immerse the probe in the Resert XL HLD solution for eight minutes, using a timer to verify appropriate time interval. The immersion should include the entire transducer shaft (up to the ring that divides the handle from the transducer shaft) but none of the handle. See diagram in the manufacturer's probe brochure. <u>The probe should not be left soaking any longer than the recommended eight minutes, as this may damage the probe covering.</u>
- Rinse well with running water and dry using a clean soft cloth.
- Plug the connector back into the machine. The probe is now ready for use with the next patient.
- Note the aforementioned cleaning regimen requires the use of three soft cloths/towels per each probe disinfection and at least five minutes to elapse on the timer before calling back a new patient.

Alternative Bleach Solution high level disinfectant

A dilute bleach soak should be created by mixing 10mL of chlorine bleach with one liter of tap water. Pour the solution into a tall soaking container with a wide bottom for stability and set the solution in the corner of the sink to minimize spillage. This is to be used only in the event that Resert XL HLD and/or Steris Monitoring Test Strips are not available for use. The dilute bleach solution needs to be remade on a daily basis. Before substituting dilute bleach solution for Resert, staff must notify the Ultrasound Program Director or Manager with the reason.

- Remove the contaminated probe cover with a paper towel and discard. Use a soft cloth to remove any excess gel from the probe.
- Unplug the probe from the machine, setting the connector (plug) carefully on a dry counter.

- Gently but thoroughly clean the probe using a mild dish soap and a soft cloth, then rinse with running water.
- Immerse the probe in the dilute bleach solution for two minutes. Note: the immersion should include the entire transducer shaft but none of the handle.
- Rinse well with running water and dry using a soft cloth.
- Plug the connector back into the machine. Probe is now ready for use with the next patient.
-

Cleaning of the abdominal probe

Abdominal probes should be cleaned and disinfected but do not generally require high level disinfection between patients.

- Remove any excess gel from the sides of the abdominal probe with a clean soft cloth. Spray probe with an ultrasound disinfectant detergent such as T-Spray and wipe thoroughly with a clean soft cloth.
- For this process, the abdominal probe does not need to be disconnected from the ultrasound machine.

Cleaning at the end of the day

Perform an extra cleaning of the probes at the end of the day to ensure equipment is left in optimal condition and ready to use. The Resert XL HLD solution should be covered. Launder any used cloths according to center and state guidelines.

Miscellaneous cleaning and service

Dust all areas of the machine twice per month or as needed with a lightly damp cloth. This is most easily accomplished with the machine turned off. The trackball may be removed and cleaned as need.
The screen may be cleaned using an alcohol swab and a soft cloth or Kimwipes. This task is best performed with the machine turned off and by working in quadrants so as to avoid streaking.

Annual maintenance of the machines may be provided by a manufacturer representative.

If trouble call service is needed, please contact agency resources to determine if the issue can be solved internally (IT or other staff) or requires a service call from the manufacturer. Contact a member of leadership to determine if service charges from the manufacturer are acceptable as the minimum trip charges are quite high.

Exporting files for storage

Files should be exported to CD/DVD or deleted from ultrasound machine hard drive storage before 50% of the hard drive capacity is exceeded. Failure to do so may result in sluggish performance of the machine.

Reference: ARMS Infection Prevention Manual

Americans United for Life

Start a new log sheet when opening new solution or test strips.

Lot #: _____ Date opened: _____ Printed expiration date: _____

Lot #: _____ Date opened: _____ Initials: _____

Printed expiration date: _____ 180 day post-open date: _____ **Discard by earliest of these two dates*

Positive Control Solution (30 mL Resert XL Solution)

Positive Results: 1) Pass / Fail 2) Pass / Fail 3) Pass / Fail

Negative Control Solution (15 mL Resert XL Solution + 15 mL tap water)

Negative Results: 1) Pass / Fail 2) Pass / Fail 3) Pass / Fail

							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	

Americans United for Life

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ____________
Date poured: ____________
End-of-life date (21 days post-pour): ____________

Discard by earliest of the two expiration dates.
Check MRC daily!

EXHIBIT 5

QUALITY ASSURANCE & RISK MANAGEMENT PLAN

Columbia Health Center
Comprehensive Health of Planned Parenthood Great Plains Inc.
711 N Providence Rd
Columbia

November 2016

Americans United for Life

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Americans United for Life

APPROVAL PAGE

COLUMBIA CLINIC
Comprehensive Health of Planned Parenthood Great Plains Inc.
711 N. Providence Rd.
Columbia, MO 65203

Clinic Risk Manager: Lead Nurse Practitioner

Quality Assurance & Risk Management Committee Members:
- Medical Director (Orrin Moore MD)
- Administrator (Vicki Casey)
- Vice President Health Center Operations (Amanda Addison)
- Director of Patient Care and Lead Clinician (Kristin Metcalf-Wilson)
- Staff physician / Consultant physician
- Director of Compliance and Quality Risk Management PPGP (Janet Smith)

This document is in accordance with the requirements of The Department of Health and Senior Services, Division of Regulation and Licensure. The following Risk Management Plan has been reviewed and is approved for use by the Chairman of the Board of Directors, President/CEO, Vice President of Health Services, and Risk Manager/Lead Nurse Practitioner.

Chairman of the Board of Directors	(see attached page) Date
President/CEO	5/15/17 Date
Administrator	5/15/17 Date
Risk Manager	5/15/17 Date

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Comprehensive Health of
Planned Parenthood Great Plains

CORPORATE BOARD RESOLUTION

Risk Management Plan (Columbia, MO and Patty Brous Health Centers)

I HEREBY CERTIFY that at a meeting of the Board of Directors of **Comprehensive Health of Planned Parenthood of Great Plains, Inc. (CHPPGP)**, a corporation organized and existing under and by virtue of the laws of the State of Missouri, held on the 6th day of December, 2016, at which said meeting a quorum was present and acting throughout, the following resolution was adopted and ever since has been and now is in full force and effect.

RESOLVED, that the Board of Directors of CHPPGP hereby approves the Risk Management Plan of CHPPGP Columbia MO and Patty Brous Health Centers which meets all Kansas statutes and regulations

In witness whereof, I have hereunto set my hand this 6th day of December 2016.

Marjorie Sable

Marjorie Sable
Board Secretary

Americans United for Life

1. PURPOSE

The quality assurance and risk management program of Columbia Center of Comprehensive Health of Planned Parenthood Great Plains is designed to assure the standard of care by the staff is maintained at an acceptable level to reduce the risk of patient injury and to minimize financial loss to the facility.

2. OBJECTIVES

The risk management program is designed to:

1. Identify areas of risk in the clinical aspects of patient care and safety.
2. Identify criteria for screening cases with risk potential regarding clinical aspects of patient care and safety.
3. Establish the investigative and evaluative process applied to cases with risk potential.
4. Assure timely intervention in events below the standard of practice.
5. Develop policies and programs to reduce risk in clinical aspects of patient care and safety.
6. Establish communication between risk management and quality assurance/improvement functions in the facility.

3. GOVERNING BODY AUTHORITY

The governing board hereby duly constitutes the Risk Management Committee and the Medical Staff Executive Committee as the committees responsible for investigating and determining applicable standards of care as required by Missouri CSR 30-30.050-060. These committees are established for the purposes of complying with risk management statutes; to evaluate and improve the quality of health care services provided in this facility. The governing board has the final responsibility and authority for the risk management program of Columbia Center of Comprehensive Health of Planned Parenthood Great Plains.

This plan was developed in accordance with provisions of the Missouri Code of State Regulations for abortion facilities. Responsibility for implementation of this plan is delegated to the Administrator. In the absence of the Administrator, the Director of Regional Health Services shall be in charge.

4. REPORTING OCCURRENCES/INCIDENTS/REVIEW OF APPROPRIATENESS OF CARE:

In accordance with CSR 30-30.060(1)(J) the quality assurance program includes all health and safety aspects of patient care and includes a review of appropriateness of care. Results of the quality assurance program are reviewed on a quarterly basis by the Administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following:

1. Completeness of clinical records
2. Incidence of morbidity and mortality
3. Intraoperative and postoperative complications (defined as including but not limited to, hemorrhage, infection, uterine perforation, cervical lacerations and retained products (19 CSR 30-30.050(1)(D))
4. All cases transferred to a hospital
5. All cased that resulted in a length of stay of more than twelve (12) hours
6. Errors in diagnosis
7. Problems in compliance with state and local laws and regulations
8. All cases in which the gestational age was determined to be beyond eighteen (18) weeks

Pursuant to RSMO 537.035, a "health care professional" is defined as a physician, surgeon, dentist, podiatrist, optometrist, pharmacist, chiropractor, psychologist, nurse, social worker, professional counselor, or a mental health professional while acting within their scope of practice.

"Risk Manager" means the individual designated by a medical care facility to administer its internal risk management program and to receive reports of reportable incidents within the facility.

When a reportable incident is identified, the person with knowledge of the incident enters it into the occurrence- reporting database for the risk management program. All reportable incidents are to be reported to the risk manager within 24 hours of discovery.

Identification of reportable incidents may be generated by, but not limited to the following methods:

- Personal Observation
- Occurrence Reports
- Infection Control Reports
- Complication Reports
- Death Reviews
- Tissue Reviews
- Patient Satisfaction Surveys
- Patient/Family Complaints
- Medical Record Reviews from all available services

Duly appointed ambulatory surgical center surveyors of the department shall be allowed to inspect the facility at any time the facility is in operation consistent with due regard for the medical condition and privacy of the on-site patients.

The risk manager shall have the authority to review all abortion facility and medical policies, procedures, records, committee minutes and actions, to make recommendations to CHPPGP administration and the medical staff and to initiate independent investigations.

5. INVESTIGATION OF OCCURRENCES

All clinical occurrence reports will be investigated by the risk manager or her/his designee and presented to the physicians' quarterly Quality / Peer Review Committee to determine whether the standard of care was met and to identify opportunities for improvement or education. The Quality / Peer Review minutes will reflect evidence of action taken as a result of the identification of the problems (CSR 30-30.060(1)(K)). All reviewers and committees shall be considered peer review committees pursuant to the provisions of CSR 537.035.

The Risk Management Committee functions as the clinic risk management committee. Members include the Medical Director, Administrator/Director of Regional Health Services, clinic Risk Manager/Director of Patient Care, Vice President of Health Center Operations, Staff Physician(s)/Consulting Physician, Director of Compliance and Quality Risk Management for PPGP.

With respect to each reported occurrence, the physicians' Quality / Peer Review Committee must determine: (1) whether individual health care providers met applicable standards of care expected in the abortion facility (2) if not, whether failure to meet those standards had a reasonable probability of causing injury to a patient; and (3) whether any action by a health care provider might be grounds for disciplinary proceedings by an appropriate licensing agency.

The activities of the Risk Management Committee shall be documented in its minutes at least quarterly.

The Risk Management committees may call upon the expertise of any abortion facility personnel or members of the medical staff in fulfilling their functions. All abortion facility personnel, administration, and members of the medical staff shall be obligated to cooperate with the Risk Management committees in acknowledgment of the joint responsibility of the medical staff, abortion facility personnel, and administration for risk management pursuant to Missouri law.

The Medical Director is responsible for notifying a physician when an adverse finding has been reported to their licensing agency; the Lead Clinician will notify nursing staff of an adverse finding and report to the Board of Nursing.

6. STANDARD OF CARE DETERMINATIONS
Columbia Clinic of Comprehensive Health of Planned Parenthood Great Plains will use the following categories: Standards of care met;

(1) Standards of care not met, but with no reasonable probability of causing injury;
(2) Standards of care not met, with injury occurring or reasonably probable; or
(3) Possible grounds for disciplinary action by the appropriate licensing agency.

*A finding of category 3 or 4 is an adverse finding and by law must be reported to the appropriate licensing agency.

"Reportable incident" means an act by a heath care provider which: (1) is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency.

8. MINIMIZING OCCURRENCES
Columbia Center of Comprehensive Health of Planned Parenthood Great Plains has established the following mechanisms to minimize occurrences:

1. Education: All new employees will receive information mandating their obligation to report reportable incidents to the risk manager. The purposes of risk management and how to report in this facility will also be explained. The Risk Management Plan will be reviewed at this time. Each employee will receive risk management in-service on an annual basis thereafter. A copy of the Risk Management Plan and a printed handout explaining the risk management law will be provided to each provider and each board member at the time of appointment and annually, thereafter. The plan will be reviewed and approved by the governing body annually. Any time the plan is amended, physicians and employees will be informed of the changes.

2. Credentialing. When, after an investigation, it is found that a reportable incident has occurred, a report will be made to the appropriate licensing agency in accordance with procedures identified in this policy. All risk management determinations will be considered in relationship to provider credentialing and the evaluation of employee performance, as appropriate.

3. Monitoring Frequency. Data relevant to reported variances/incidents will be compiled by the risk manager in statistical summary and will be presented quarterly to the Director of Compliance and Quality Risk Management to be used for identifying trends in practice and patient care. The Quality Management Committee shall analyze the frequency and causes of incidents and pursue measures to minimize recurrence through the active cooperation of clinic staff, medical staff and administration. Statistical data and summaries shall also be reported to the governing board at least quarterly.

*Data obtained for the purposes of risk management and quality assurance pursuant to CSR 30-30.060 shall be considered confidential information and not discoverable in a court of law.

4. Facility Actions. Internal facility actions may be taken as a result of investigation and data compilation and shall be in accordance with medical staff bylaws, agency policy, and governing board bylaws.

8. PLAN
A current copy of the Quality Assurance and Risk Management Plan shall be included in the employee policy manual and the bylaws of the governing board and medical staff. The plan will be reviewed annually. The Missouri Department of Health and Senior Services will be notified in writing of any change in the designation of the administrator of the facility.

9. CONFIDENTIALITY

Any person or committee performing any duty pursuant to this plan shall be designated as a peer review officer or committee pursuant to RSMO 537.035 and the amendments thereto.

All reports and records made pursuant to RSMO 537.035 and amendments thereto, shall be confidential and privileged. Such reports and records shall not be subject to discovery, subpoena or other means of legal compulsion for their release to any person or entity and shall not be admissible in any judicial or administrative action, for failure to provide appropriate care, other than a disciplinary proceeding by the appropriate state licensing agency.

Pursuant to RSMO 537.05, no person who was in attendance at any peer review committee proceeding shall be permitted or required to disclose any information acquired in connection with or in the course of such proceeding, or to disclose any opinion, recommendation, or evaluation of the committee or board, or any member thereof.

No abortion facility personnel, member of the medical staff or facility board member shall disclose information concerning reportable incidents except to their superiors, abortion facility administrator, the risk manager, the appropriate abortion facility and medical staff committee or the licensing agencies, unless authorized to do so by the risk manager.

10. INTERFERENCE WITH RISK MANAGEMENT PROCESS AND RETRIBUTION FOR REPORTING

Attempts by any employee of the facility or members of the medical staff to inhibit or prevent any other employee or medical staff member from reporting what they believe meets the definition of a reportable incident, shall not be tolerated, and will result in reprimand, suspension, or termination of any person who does so try to inhibit or prevent.

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QUALITY ASSURANCE PROGRAM REVIEW FOR THE CHPPGP COLUMBIA CLINIC

__ Quarter 20__

To be reviewed quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body.

MEDICAL ABORTION COMPLICATIONS FOR THE COLUMBIA CLINIC:

Total # of Medical Abortions =
Total # of Medical Abortion Complications =
Total % of MAB Complications =

Physician	Dr. McNicholas	Dr. Yeomans
Procedures (denominator)		
Failed MAB		
Infection		
Retained POC/blood clots & debris		
Hematometra		
Incomplete MAB		
Hospital Transfers from clinic		
Hospital Transfers from home		
Undiagnosed Ectopic		
Non-ectopic "errors" in diagnosis		
Hemorrhage/Heavy bleeding requiring tx		
Timely/Completeness of clinical records audit results:		
Death		
Total number of complications (numerator)		

SURGICAL ABORTION COMPLICATIONS FOR THE COLUMBIA CLINIC:

Total # of Surgical Abortions =
Total # of Surgical Abortion Complications =
Total % of Surgical Abortion Complications =

Physician	Dr. McNicholas	
Procedures (denominator)		
Failed surgical procedures		
Infection		
Retained POC/blood clots & debris		
Hematometra		
Perforation/laceration		
Hospital Transfers from clinic		
Hospital Transfers from home		
Undiagnosed Ectopic		
Non-ectopic "errors" in diagnosis		
Hemorrhage/Heavy bleeding requiring tx		
Timely/Completeness of clinical records audit results:		
Death		
Total number of complications (numerator)		

PROBLEMS WITH COMPLIANCE WITH STATE AND LOCAL LAWS AND REGULATIONS REGARDING ABORTION:

GOOD CATCHES:

Risk Management Review Date _____

Members Signatures present:

_____ Medical Director

_____ Staff Physician

_____ Staff or Consulting Physician

_____ Administrator

_____ Director of Patient Care

_____ Director of Compliance & Quality Risk

Date of quarterly Review by PPGP Board of Directors: _____

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EXHIBIT 6

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HENRY SCHEIN®

135 DURYEA ROAD
MELVILLE, NY 11747

SHIP TO:

PP-Columbia Center
711 N Providence Rd
Orrin Moore
Columbia MO 652034357

BILL TO:

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park KS 662111303

Order Confirmation

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

ACCOUNT #	TOTAL AMOUNT
2214493	95.21
ORDER NUMBER	ORDER DATE
52037758 SE	05/11/17
PAGE #	...
1	

LINE NO	ITEM CODE	UNIT SIZE DRUG CLASS	DESCRIPTION & STRENGTH	QTY. ORD SHIPPED	SHIPPING DETAILS CUSTOMER P.O.#	UNIT PRICE	EXTENSION
1	9879426	100/Bx PU	Needle Disposable 21gx2" 05/11/17 1.000	1 1	SHIPPING COL-AB-05112017	15.74	31.48
2	2170030	Ea PU	Formalin 10% NBF 1 Gal 05/11/17 2.000	2 2	SHIPPING COL-AB-05112017	28.12	56.24
3	1089349	Ea	Hand Pump f/Hibiclens Gallon 05/11/17 1.000	1 1	SHIPPING COL-AB-05112017	1.88	1.88
4			SHIPPING AND/OR HANDLING			1.75	1.75
5			TAX			3.86	3.86

Included in the below freight charge is a fuel/handling surcharge. For the current terms of sale goto http://www.henryschein.com/us-en/MEDICAL/legalTerms.aspx

ACCOUNT #	TOTAL AMOUNT
2214493	95.21
ORDER NUMBER	ORDER DATE
52037758 SE	05/11/17
PAGE #	...
1	

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EXHIBIT 7

ING SLIP

DATE: 04/21/2017

85092812BP04654612

McKESSON

TO: 56799187	BILL TO: 54565244	FROM:
NNED PARENTHOOH GREAT PLAINS 1 N PROVIDENCE RD COLUMBIA, MO 65203	PLANNED PARENTHOOD 4401 W109TH ST STE 200 OVERLAND PARK, KS 66211	MCKESSON MEDICAL-SURGICAL INC(KANSAS CTY KANSAS CITY PC # 003 1405 N. CHOUTEAU KANSAS CITY, MO 64120 AB
CUST P.O. NUMBER: COL-AB-04202017-1 ORDERED BY: EJJ7ED0	INVOICE NUMBER: 1836809 **ORDER NUMBER: 85092812 SO** ORDER DATE: 4/20/2017	DISTRICT 2001031644 LICENSE:
FOB Destination	Regulatory License: 2004030009	

LN #	Item / Mfg Number	Qty Ordered	UOM Bin Loc	Shipped	To Follow	Description Vendor	Cust Item #
2	848309 & 00562780505	2	BX	2	✓	RHOGAM, SYR PLUS ULTR FILTERED 300MCG (5/BX) KNDBIO	/IBX848309

For Drug Supply Chain Security Act (DSCSA) inquiries, please log on to McKesson SupplyManager℠, then select "DSCSA Traceability Reporting" under the "Reports" tab. For questions, email DSCSARegulatory@McKesson.com. McKesson's Terms of Sale shall apply to all purchases. Any discrepancy between any order placed under this Agreement and McKesson's corresponding shipment must be reported to McKesson for resolution within ten (10) Calendar days of McKesson's invoice date except for price or payment discrepancies which shall be reported to McKesson for resolution within thirty (30) days of McKesson's invoice date. Prices exclude taxes and service fees. Failure to report within the designated time shall constitute a waiver of any claims due to such discrepancy.

Contact your Customer Service Center if Safety Data Sheets are needed.

Rx Package insert information can be found at the website, http:DAILYMED.NLM.NIH.gov/dailymed/about.cfm. If you have trouble accessing the website and need package insert information, please contact Customer Service and request a copy.

NOTE - '*' Next to Line Number Indicates Shipping from Another Location
'**' Next to Line Number Indicates Line Under Review

(CONTINUED NEXT PAGE)

TA 4-26-17

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EXHIBIT 8

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Medical AB SUPPLY LIST

Craig Medical
Eldon Cards DKS RhD-25

Immucor – 1-800-829-2553
Eldon Card Control
Panoscreen III Item #0002381

Henry Schein
HemoCue Controls (Low/High)
HemoCue Microcuvettes
Lancets 21 G Safety
Digital Ear Thermometer
Thermometer Covers
Ultrasound Gel
Ultrasound Probe Covers
Sani-Cloth Disinfectant Wipes
Non Latex Condoms
PTU's
Paper Bags
Drapes
Urine Cups
Drinking Cups
Urine Dip Sticks

PDRX
Zithromax – 500 mg
Ondansetron 4 mg
Tylenol 3 – 30 mg
Cytotec (Misoprostol) 200 mcg tablets
Rhogam (1/2 dose)

Smith Medical
Mifeprex – 200mg

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First Trimester Surgical AB List

Ibuprofen 800 mg

Azithromycin 500 mg

Emergency medications/Crash cart – see Arms Emergency Procedure Guide

Valium 10mg I pill by mouth-given before procedure

Methergine-0.2mg/ml

Lidocaine HCl- 1% - 10ml syringes

22G Spinal Needle

Non sterile 4 x 4 gauze pads

Lubricating jelly packets

Hibiclens

Flexible Cannulas Size 6-12

Rigid Cannulas Size 6-14

Suction tubing

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Columbia HC

Pharmaceuticals	Count	Expiration Date	Pharmaceuticals	Count	Expiration Date
Crash Cart			**Medications:**		
Month/Year May 2017			*Ammonia Capsules (6)	10	6/19
SUPPLIES:			Atropine Sulfate 0.4 mg/ml	1	4/18
*O2 tank	Full		Diazepam 10 mg	100	6/17
*3cc syringes with 21g/22g needles	9	N/A	Diazepam 5 mg/ml vial	10	9/17
*Adult Bag Valve Mask and Tubing	1	N/A	*Diphenhydramine Hydrochloride (Benadryl) 25 mg po x 6	100	12/17
AED On Cart w/ Adult Pads	✓		*Diphrenhydramine Hydrochloride (Benadryl) 50mg/ml (1ml vial x 4)	4	10/18
*Alcohol Preps	12	N/A	*Epi-pen	1	8/17
*Angiocaths – 18, 20, ~~22~~	6	4- 9/19 2 - 4/19	*Epinephrine 1:1000 Ampoules x 4	4	8/17
Endotrachial tubes	6	5.0 = 7/19 ~~8.0~~ = 5/20 7.5 = 3/20	*Flumazenil 5ml vial 0.1 mg/ml	10	10/18
*Exam Gloves (non latex)	✓	NA	Lidocaine HCL 1%	1	2/2018
*IV bag – normal saline	2	10/17	*Methylergonovine 0.2 mg/ml vial	10 In Recovery fridge	6/2018
*IV bag - Ringers Lactate	4	11/18	*Misoprostol 200 mcg	8 tabs	~~5/17~~ 5/18
*IV tubing	2	12/19	*Naloxone vial 0.4mg/ml	1	11/17
IV start Kit N/A			*Oxytocin 10 units/ml	2	1/18

Laryngoscope	1	N/A	Solumedrol	1	8/20
*one-way valve mask			*Vasopressin 20 units/ml vial	25	7/18
*Oral Airway Set	1	N/A			
*nasal cannula	1	N/A			
*Non rebreather Face Mask	1	N/A			
*Sterile 4x4 gauze	2	N/A			
Scissors	1	N/A			
Tourniquet	1	N/A			
*Tape Plastic/Paper					
*TB syringes	5	N/A			
			Nurse:		

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Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

August 11, 2017

Amanda Addison (Amanda.addison@ppgreatplains.org)
Comprehensive Health of Planned Parenthood Great Plains
711 North Providence Road
Columbia, Mo 65203

Re: Comprehensive Health of Planned Parenthood Great Plains – Columbia Revisit Survey

Dear Ms. Addison:

The Department received the application for licensure of the Columbia Planned Parenthood location as an abortion facility. Department staff conducted an onsite survey of the facility on October 11, 2016 to determine compliance with the terms of the 2010 settlement agreement and applicable statutes and regulations. As a result, on November 2, 2016, your facility was provided with a list of regulatory items that were not in compliance.

After the facility submitted a complete response and documentation regarding correction of the items that were not in compliance, the Department performed an onsite revisit of the facility on July 25, 2017.

Listed below are items the revisit survey indicated were still not in compliance. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued.

19 CSR 30-30.0601(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.

The facility failed to demonstrate compliance with facility's established Infection Prevention Program, based on Association for the Advancement of Medical Instrumentation (AAMI) and Centers for Disease Control (CDC) standards. Specific findings:

1. The facility failed to follow the manufacturer's instructions for use (IFU) for routine care of the sterilizers.

(AAMI 9.4 Routine Care: Sterilizers should be inspected and cleaned daily according to the manufacturers' written instructions. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturers' written IFU.)

2. The facility failed to maintain a separate autoclave log with the required components tracked for each of two sterilizers.

(AAMI 10.3.2 Sterilizer records: For each sterilization cycle, the following information should be recorded and maintained: Lot number; Specific contents of the lot or load, including quantity, department, and a specific description of the items [e.g. towels, type/name of instrument sets]; Exposure time and temperature, if not provided on the sterilizer recording chart; Name or initials of the operator; Results of biological testing, if applicable; Any reports of inconclusive or nonresponsive chemical indicators found later in the load.)

3. The facility failed to maintain a record of sterilizer maintenance and repair.

(AAMI 9.7 A maintenance record, in either paper or electronic format, should be kept for each sterilizer. At least the following information should be recorded:

a) The date on which service was requested;
b) The model and serial number of the sterilizer;
c) The location of the equipment (if applicable);
d) The name of the individual from the facility who requested and authorized the service;
e) The reason for the service request;
f) A description of the service performed ;
g) The types an quantities of parts replaced;
h) The name of the person who performed the service;
i) The date the work was completed;
j) The handwritten or electronic signature and title of the person who acknowledged completion of the work; and
k) The results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service.)

4. The facility failed to have written processes for reprocessing and/or quarantine of instruments following positive biological indicators, as well as consecutive biological testing following sterilizer failure and repair.

5. During an interview with facility advanced practice nursing staff at the time of the revisit, staff acknowledged the problems with adequate documentation and clear adherence to the AAMI standards.

Please respond in writing providing evidence/documentation that each of these items has been fully addressed and corrected.

If you have further questions, you may contact our office at 573-751-6083 or via email at the address noted below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Planned Parenthood®
Care. No matter what.

Comprehensive Health
4401 W. 109th St Suite 100
Overland Park, KS 66211
p: 913.345.1400 f: 913.345.2820
www.PPGreatPlains.org

Comprehensive Health of
Planned Parenthood Great Plains

August 16, 2017

John Langston
Bureau of Ambulatory Care
MO Department of Health & Senior Services
POB 570
Jefferson City MO 65102

Dear Mr Langston:

Please find attached our responses to the items regarding our infection prevention program that are needed to bring us into compliance.

1. Exhibit A
   Autoclave Policy referencing the requirement to follow the manufacturer's instructions for routine care of the autoclave. The policy includes cleaning instructions for the autoclave.

2. Exhibit B
   Updated "Autoclave Log". The second autoclave that was put into service while waiting for the repair of the first autoclave, has been taken out of the clean room and put in storage. If the second autoclave needs to be put in service, a new and separate autoclave log will be implemented.

3. Exhibit C
   - "Procedure to Respond to Autoclave Malfunction/Positive Spore Test/Maintenance checklist has been implemented that includes all information that is required to be documented after an autoclave fail or maintenance has been performed.
   - Maintenance record of autoclave repair done on 06/20/17.

4. Exhibit D
   "Autoclave Policy and Procedure for Autoclave Maintenance/Positive Spore Test" addresses reprocessing and/ or quarantine of instruments following a positive spore test, as well as consecutive spore testing requirements following a failure.

5. Exhibit E
   Staff Education/Reeducation Form
   Columbia health center staff have been educated regarding new autoclave and autoclave failure policies.

Please let me know if you need anything further.

Sincerely,

Amanda Addison
Vice President of Health Services
Planned Parenthood Great Plains
Amanda.addison@ppgreatplains.org
PH: 913-345-4659

Americans United for Life

EXHIBIT A

Planned Parenthood®
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Planned Parenthood Great Plains

Policy: Inspecting and Cleaning the Inside of the Autoclave

Originator: Health Services

Approval Date: July 2017

Policy:

1. Clinic staff will follow the autoclave policies and procedures described in the ARMS Infection Prevention Manual. The policies described here provide additional clarity on how to clean the autoclave.
2. It is the policy of PPGP to inspect and clean the autoclave by following the manufacturer's instructions. Each autoclave should have the manufacturer's instructions posted next to it.
3. Record the manufacturer's inspection and cleaning instructions in the autoclave log notebook.
4. The autoclave must be inspected and cleaned at the end of each day in order to remove any residue that settles onto the surface. Rationale: If the autoclave is not cleaned daily, residue may build up and become aerosolized in the steam, compromising the sterilization process.
5. The autoclave must be inspected and cleaned at least weekly with detergent or as recommended by the manufacturer.
6. The water in the autoclave must be changed at least monthly or as recommended by the manufacturer.
7. Each time the autoclave is cleaned (daily, weekly and as needed), document the cleaning or water change in the autoclave log. Record the brand of detergent that is used.

Reference:

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/sterilizing-practices.html

Comprehensive health of Planned Parenthood Great Plains
Policy on Cleaning the Autoclave

The inside of the autoclave must be wiped down at the end of each day in order to remove any residue that collects inside the chamber and around the door opening.

The autoclave must be cleaned at least once a week with Pelton's Original Formula Omni-Cleaner ("detergent") and distilled or demineralized water.

Clean the outside of the autoclave with water and a non-chlorinated detergent. Do not use chlorine, steel brushes, stainless steel, or steel wool. Always rub in the direction of the metal grain pattern. If the surface is contaminated, clean with a 5% solution of warm, oxalic acid.

When cleaning saline solutions, it is imperative that the autoclave be cleaned after each use (in order to get salt residue out of the autoclave before the salt can corrode the stainless steel finish).

- Mix 12 ounces of detergent in 1 gallon of water.
- Drain water from the autoclave reservoir.
- Refill reservoir with detergent solution.
- Run one, 20 minute sterilizing cycle. Do not sterilize instruments while cleaning autoclave.
- Drain cleaning solution from reservoir and chamber.
- Rinse thoroughly with clean, mineral-free water.
- Run a rinse cycle for 15 minutes.
- Drain rinse solution.
- Wipe inside of boiler thoroughly.
- If there are lime deposits inside the chamber, make sure the chamber is cool and clean with water, plastic or nylon scouring pads, and non-chlorinated detergent.
- Refill reservoir with clean, mineral-free water.
- The autoclave is now ready for use.

EXHIBIT B

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AUTOCLAVE LOG for Month _____

Clinic: _____

Biomedical company: _____ **Last Calibration Date:** _____

Date of Weekly Cleaning & Water Change: _____

Daily inspection & wipe inside and door opening:

Week 1/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 2/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 3/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 4/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 5/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat

Dates of weekly spore testing & results reviewed by health center manager: **(an inconclusive or nonresponsive result counts as a failure*)**

date of week 1_____ **pass / fail (circle one)**

date of week 2_____ **pass / fail (circle one)**

date of week 3 _____ **pass / fail (circle one)**

date of week 4_____ **pass / fail (circle one)**

date of week 5_____ **pass / fail (circle one)**

*if test fails, see "responding to autoclave malfunction" checklist in Lab Manual

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials

Americans United for Life

EXHIBIT C

Check if done	Procedure to Respond to Autoclave Malfunction/ Positive Spore Test or when maintenance is needed	date	time
	If the clinic is notified of a positive biological indicator (ie failed spore test), or if or if maintenance is needed, remove the autoclave from service. Put a sign on the autoclave telling staff not to use it and the reason why. Date and time the sign. Immediately notify the health center manager. If there was a positive spore test, make sure all items that were sterilized since the last satisfactory spore test remain quarantined. Borrow sterile items from another clinic if necessary. (Autoclave does not need to be removed from service if biomed is performing the routine yearly inspection and maintenance).		
	Make an entry in the autoclave log that the autoclave is out of service and no items are being sterilized in it.		
	Date when biomed service was requested:		
	Model & serial number of sterilizer:		
	Location of sterilizer:		
	Name of clinic staff who requested and authorized service:		
	Reason for service request:		
	Name of bio med service called & name of person spoken with:		
	If the clinic borrows a back-up autoclave to sterilize instruments, it must pass 3 spore tests before being used to sterilize items. The second autoclave must have its own autoclave log. If an autoclave was borrowed: Date: Model & serial number:		
	Name of biomedical tech who serviced the autoclave:		
	Date and time of service:		
	Description of service performed:		
	Types and quantities of parts replaced:		
	Date work was completed:		
	Attach the handwritten or electronic signature and title of the clinic staff who acknowledged completion of the work		
	Document the results of any post-test maintenance testing performed, if		

	needed, before the sterilizer was returned to service, including:		
	After the biomedical tech clears the autoclave to return to service, run 3 consecutive spore tests. For pre-vacuum autoclaves, also run 3 Bowie-Dickie tests. On the autoclave log, record the date and times the tests were run and mailed in.		
	Do not use the autoclave until all tests are satisfactory. Put a sign on the autoclave telling staff not to use it until the spore tests come back satisfactory. Make sure the health center manager and all staff are aware. Alternative: Quarantine sterilized items until the 3 spore tests come back satisfactory and are reviewed by the health center manager.		
	When the 3 spore tests are returned, are satisfactory, and are reviewed by the health center manager, the autoclave may be used to sterilize items. Date autoclave put back in service: Health Center Manager signs here to attest the 3 satisfactory spore tests were reviewed.		
	Comments:		

This check list also located in the Lab Manual (Chapter 3: Quality Assurance).

Reference:

ARMS Infection Prevention Manual

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/sterilizing-practices.html

Association for the Advancement of Medical Instrumentation (AAMI) standards

Note: Missouri licensing survey team requires adherence to AAMI standards

Invoice

BESS Inc.
4203 East 109th Street
Kansas City, MO 64137
913 696-9977 fax 913 696-9981

Date	Invoice #
6/20/2017	8204

Bill To:

Planned Parenthood of Great Plains
4401 W 109th St, suite 200
Overland Park, KS 66211

Service To

711 North Providence Rd
Columbia, MO 65203

P.O. No.	Terms	Project
	Net 30	

Quantity	Description	Rate	Amount
	Pelton Crane Magnaclave Model MC Serial Number A6-5641 Overheating issues Disassembled and cleaned obstructed valve, reassembled and tested complete cycle, passed test		
1.5	Labor - Consultation	75.00	112.50T
4	Travel Time	60.00	240.00
	Tax Exempt - Certificate on file	0.00%	0.00

GP-84000 - HCFP-COL

RECEIVED JUN 21 2017

Total $352.50

Americans United for Life

EXHIBIT D

Planned Parenthood®
Care. No matter what.

Planned Parenthood Great Plains

Policy: Autoclave Policy and Procedure for Autoclave Maintenance/ Positive Spore Test

Originator: Health Services

Approval Date: July 2017

Policy: Planned Parenthood Great Plains (PPGP) clinic staff will follow the autoclave policies and procedures described in the ARMS Infection Prevention Manual.

It is PPGP's policy to run a spore test in each autoclave once a week. All items sterilized in the autoclave will be quarantined until the spore test comes back satisfactory. (Example: the spore test is conducted on May 1 and the test results are received at 8:00 am May 3. All instruments sterilized between May 1 and 7:59 May 3 are quarantined until the satisfactory spore test is reviewed). Rationale: Items must not reach patient until the test result confirms the autoclave killed all the spores in the test kit.

This policy and procedure describes what to do when staff have reason to believe the autoclave has failed, either by receiving a positive biological (unsatisfactory spore test) or by suspecting a mechanical malfunction (e.g. noticing a burning odor). This policy and procedure also describes the process that must be followed for autoclave maintenance.

Process in the Clinics:
When the autoclave is first installed and any time it is redesigned, after a repair, and after a sterilization failure has occurred, staff must run 3 satisfactory spore tests to ensure it is functioning prior to sterilizing items. The autoclave must be tested after it is relocated or there is a water line break with an autoclave that utilizes city water (Comp Health Overland Park autoclave).

When three consecutive spore tests come back satisfactory the autoclave can be used to sterilize items. Any items processed during the three evaluation cycles should be quarantined until the test results are satisfactory.

Spore tests, chemical tests, Bowie-Dickie tests and autoclave print-outs should be kept in the autoclave log for two (2) years.

EXHIBIT E

STAFF EDUCATION/REEDUCATION FORM

Clinic: Columbia **Date:** 8/15/2017

Education/Reeducation Topic: Autoclave

Criteria presented:
- IP manual changes
- Autoclave Policy
- Autoclave log

Staff in attendance (please sign name):

Identified areas of concern (if any):

Corrective Action Plan (how will staff be monitored):
- HCM/or NP will monthly check log, and weekly check to ensure sterilization strips are sent
- NP will ensure spore testing is Pass, and will follow protocol if there is a fail.

Clinician signature:

Clinic manager signature:

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

October 3, 2017

Vicki Casey
Comprehensive Health of Planned Parenthood Great Plains, Inc.
711 North Providence Road
Columbia, MO 65203

Re: Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia survey

Dear Ms. Casey:

Please see attached results of the recent follow-up survey of August 28, 2017. Your facility is now in compliance with current legal requirements for licensure.

Please retain this material for your own records. The abortion facility license is attached, effective date October 3, 2017.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 08/28/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An onsite Licensure revisit survey was conducted on 08/28/17. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	{L 000}		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	10/11/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PARENTHC	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments A full licensure survey was conducted at the facility on 10/11/16 to determine compliance with state requirements for Abortion Providers, which includes state rules 19 CSR 30-30.050-30.070, applicable portions of Chapter 197 and 188, as well as the 2010 settlement agreement between DHSS and the facility. The survey was conducted prior to issuing a license for the facility to resume providing abortion services at this location. A Statement of Deficiencies (SOD) in the form of a findings letter was sent to the facility instead of a Form 2567 in early November 2016. Following receipt of this findings letter, in early December 2016, the facility filed suit against DHSS in federal court (Case No. 2:16-cv-04313-HFS), primarily regarding DHSS ' s ongoing enforcement of Missouri requirements for ASC standards and physician privileges, following the SCOTUS decision in Whole Woman ' s Health v. Hellerstedt. As of 1/6/17, no formal response to the SOD has been received, no license has been issued. This survey process will be suspended/closed, and no further licensure activity planned pending the outcome of the federal case. This entry is being made for record-keeping and historical purposes, and should not be considered part of the formal SOD. Addendum: October 2017: After multiple court proceedings, DHSS did receive an SOD and conducted sufficient follow up activities to ensure that all requirements were eventually determined to be met. The Columbia location was eventually granted an Abortion Facility license effective date 10/3/2017.	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	10/11/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PARENTHC	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Continued From page 1 Survey process closed. BAC Admin.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

June 18, 2018

Brandon J. Hill, PhD
President and CEO
Comprehensive Health of Planned Parenthood Great Plains (re: Columbia Clinic, A004)
4402 W 109th Street, #100
Overland Park KS 66211

Dear Dr. Hill:

This is in response to your letter requesting a waiver of the regulatory requirement for a pelvic exam prior to a medical abortion (19 CSR 30-30.060(2)(D)), *specifically for the Columbia, Missouri location (A004).* The department has considered the request and determined that the requirement is proper. Additionally, there is no provision in the abortion facility regulations that authorizes the department to grant waivers of this requirement. The 2010 settlement agreement between DHSS and Planned Parenthood exempts only the Kansas City location from this requirement. Therefore, the request is denied.

Sincerely,

John Langston

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

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Care. No matter what.
Comprehensive Health of
Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

June 14, 2018

Dr. Randall Williams
Missouri Department of Health and Senior Services
912 Wildwood
Jefferson City, MO 65102-0570

Via U.S. Mail and electronic mail to randall.williams@health.mo.gov

Dear Dr. Williams:

It has come to our attention that the Department of Health and Senior Services (DHSS) has begun to require all abortion patients to submit to a pelvic exam prior to having an abortion, including a medication abortion. On behalf of Comprehensive Health of Planned Parenthood Great Plains (Comprehensive Health), which operates licensed abortion facilities in Kansas City and Columbia, we are applying for a waiver of the state mandated pelvic exam requirement, 19 CSR 30-30.060(2)(D), prior to medication abortions. As the Department is aware, it has already waived the requirement as to our Kansas City facility; therefore, our request seeks to extend the waiver to our Columbia facility.

The health and safety of women is our mandate. The most recognized national medical experts on women's health and abortion – the American College of Obstetrics and Gynecology (ACOG), Planned Parenthood Federation of America, and the National Abortion Federation – consider a pelvic exam prior to a medication abortion medically unnecessary except in very specific circumstances. These experts have established the standards of all American gynecologic care based on an expansive review of care provided across a variety of settings, circumstances, and involving millions of patients. In addition, recently the National Academies of Sciences, Engineering and Medicine published a comprehensive report on the safety and quality of abortion care in the United States, which confirmed that the clinical assessments required prior to medication abortion do not include a pelvic exam for all women.

The State of Missouri, in dictating the policy of a pelvic exam prior to medication abortion for every patient, regardless of her individual, medical and personal history, is mandating a requirement that goes against an evidence-based approach to medical care for women, potentially violates ethical and medical consent practices, and forces women to submit to an intrusive examination that is not necessary to ensure their health and safety. Our physician at our Columbia health center does not believe she can ethically require women to undergo a pelvic exam prior to medication abortion, unless such an examination is medically indicated based on patient-specified issues.

Further, as our society grapples with the many concerns raised by the "Me Too" movement and alarming increased instances of assaults perpetrated under the guise of "medical care", including those committed by Dr. Larry Nassar and University of Southern California physician

Dr. George Tyndall whose behavior during pelvic exams was deemed outside the scope of current medical practices, we believe it is imperative that state officials be committed more than ever to the protection of women's bodily integrity. Our commitment is unwavering, and we are hopeful that the Department will be reasonable in its interpretation of this requirement.

The Department has historically elected not to enforce this requirement for medication abortion procedures, making clear that it is unnecessary for the health and safety of women. In prior annual inspections by the Department, we have never been issued a citation on this issue by state surveyors. Indeed, email communications between state surveyors indicate they accepted that pelvic examinations were unnecessary because sonograms are performed for every patient. In addition, as stated above, our Kansas City health center is exempted from performing pelvic exams prior to a medication abortion when such an exam is not medically indicated. Moreover, any hospital that provides a medication abortion to a woman does not need to abide by this requirement as it is a standard specific only to abortion facilities. Thus, there is no basis to conclude that the pelvic examination requirement is necessary for women's health. On the contrary, the requirement only serves to place an additional, offensive burden on abortion access in Missouri.

Losing the option of medication abortion in Missouri will negatively impact the health and safety of women by forcing patients to consider surgical options despite reasons to prefer medication procedures, postpone their procedures to later gestational ages, or not access abortion care at all. As the Department recognized in the emergency complication-plan regulation, medication abortion may be medically appropriate over surgical abortion for some women.

I implore you to grant Comprehensive Health a waiver from the pelvic exam requirement for women choosing medication abortion. Thank you for your attention to this critical health matter. I am also available at any time for a discussion of this important matter. In addition to this letter, please consider the supporting documentation attached to Reproductive Health Services of Planned Parenthood of the St. Louis Region's similar request for a waiver.

Sincerely,

Brandon J. Hill, PhD
President & CEO
Comprehensive Health of Planned Parenthood Great Plains

cc: John Langston, Bureau of Ambulatory Care, DHSS
Amanda Addison, Vice President for Health Services, Comprehensive Health

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 30, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains
711 N Providence Road
Columbia, MO 65203

RE: ***Licensure Survey TKOR11***

Dear Vicki Casey:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***August 14, 2018*** in connection with the ***State Licensure*** requirements as they pertain to abortion centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Enclosure

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 08/13/18 to 08/14/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L1081	19 CSR 30-30.060(1)(B)(3) The administrator shall be responsible, plan The administrator shall be responsible for developing a written plan for evacuation of patients and personnel in the event of fire, explosion, active shooter, or other disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. Disaster drills with participation of all staff shall be conducted and documented at least annually. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that all staff participated in drills and were knowledgeable about the plan. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's document titled, "Quarterly Fire Drill Report," dated 02/18/18, showed that the facility had a fire drill on that date. The previous fire drill was held on 04/05/17. 2. During an interview on 08/14/18 at 2:33 PM,	L1081		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1081	Continued From page 1 Staff C, Health Center Manager, stated that: - She had been employed at the facility since March. - She had not participated in a fire drill or emergency drill since starting at the facility. - The facility was to have fire drills or emergency drills twice per year. 3. During an interview on 08/14/18 at 2:50 PM, Staff F, Licensed Practical Nurse, stated that: - She was from a staffing agency but worked full time hours at the facility and had done so since 07/19/18. - She had not participated in a fire or emergency drill since starting at the facility. - When asked if she knew where the designated safe spot during a tornado was she replied she did not know. - When asked if she knew how to activate the fire alarm she stated she did not know.	L1081		
L1084	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the	L1084		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1084	Continued From page 2 exam rooms; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. - Recommendation II.b. * All horizontal surfaces in the operating room (OR) (e.g., furniture, surgical lights, booms, equipment) should be damp dusted before the first scheduled surgical or other invasive procedure of the day. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. 2. Review of the facility's "Infection Prevention	L1084		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1084	Continued From page 3	L1084		

Manual," dated 08/15, showed infection control resources included:
- Centers for Disease Control (CDC);
- Association for Professionals in Infection Control and Epidemiology (APIC); and
- AORN.

3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed:
- Thoroughly clean all surfaces that are used in patient care areas.
- Avoid cleaning methods and machines that re-suspend dust from surfaces, especially in patient care areas.
- All areas of the clinic should be kept clean and free from excess clutter.
- The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment.

4. Observation on 08/13/18 at 10:40 AM of the procedure room showed the metal suction machine cabinet had numerous rusted areas (uncleanable surface).

During an interview on 08/14/18 at 1:25 PM, Staff C, Health Center Manager, stated that she had cleaned the metal suction cabinet and confirmed it was rusted.

5. Observation on 08/13/18 at 10:45 AM of the recovery room medication supply room showed:
- A metal shelf unit with five pressed wood shelves, the shelves were dusty;
- A pressed wood shelf leaning against the wall;
- The floor under the shelf unit was dusty; and
- There was a box containing 25 expired hCG Urine Cassette Cultures (urine pregnancy test)

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1084	Continued From page 4 expiration 03/18, on the floor behind the shelving unit. During an interview upon the observation, Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) stated that housekeeping staff did not have access to the room and confirmed that the urine pregnancy tests were expired. 6. Observation on 08/13/18 at 2:10 PM of exam room 1 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue which created a noncleanable surface; - Dust and debris and a brown stained area in the cabinet under the sink ; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; and - The gooseneck lamp had a dried peeling label and adhesive residue. 7. Observation on 08/13/18 at 2:15 PM of exam room 2 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue; - Dust and debris and a grayish black discolored area in the cabinet under the sink and an area where the base of the cabinet was peeling; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; - A plastic glove box holder had dust on the top	L1084		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

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L1084	Continued From page 5 that left a visible mark when a finger was drawn through; and - The cabinet under the sink had peeling and/or missing laminate at the bottom outer corner. 8. Observation on 08/13/18 at 2:20 PM of exam room 3 showed the top edges of two picture frames were dusty. 9. During an interview on 08/13/18 at 2:25 PM, Staff C stated that: - The housekeeper did not go into the recovery room supply cabinet; - Peeling laminate could not be disinfected; and - They planned to purchase new tables for the exam rooms. 10. Observation on 08/13/18 at 2:30 PM of the soiled area showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue.	L1084		
L1090	19 CSR 30-30.060(1)(B)(7)(E) Provisions for licensed personnel to have cur Provisions for licensed personnel to have current cardiopulmonary (CPR) training so that at least one (1) licensed and trained personnel is at the facility at all times when patients are present for abortions; and This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that licensed personnel maintained current cardiopulmonary (CPR) training for one (B) of two licensed staff personnel records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four	L1090		

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L1090	Continued From page 6 procedures. Findings included: 1. Review of the facility's policy titled, "Personnel Files," dated 05/15, showed personnel information collected by the facility included first aid/CPR cards. 2. Review of Staff B, Registered Nurse (RN), Nurse Practitioner's (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) personnel file showed her CPR training had expired 04/20/18. 3. During an interview on 08/14/18 at 1:30 PM, Staff B stated that: - She was required to maintain current CPR. - She was not aware her CPR certification had expired.	L1090		
L1101	19 CSR 30-30.060(2)(B) Each patient shall be given all the informati Each patient shall be given all the information required by sections 188.027 and 188.039, RSMo, in the formats and timeframes required, by the type of professional required. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to ensure that the physician who was to perform or induce the abortion or a qualified professional as required by law (Section 188.027.1(1), RSMO, a physician, physician assistant, registered nurse, licensed practical nurse, psychologist, licensed professional counselor or licensed social worker licensed or registered and working under the	L1101		

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L1101	Continued From page 7	L1101		

supervision of the physician performing or inducing the abortion) informed the woman of the gestational age of the fetus at the time of abortion for ten (#1, #2, #3, #4, #5, #6, #7 #8, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures.

Findings included:

1. Review of Missouri law 188.027 RSMo, showed consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion:
(1) The physician who is to perform or induce the abortion, a qualified professional, or the referring physician has informed the woman orally, reduced to writing, and in person, of the following:
(f) The gestational age (term used during pregnancy to describe how far along the pregnancy is) of the unborn child at the time the abortion is to be performed or induced; and
(g) The anatomical (relating to bodily structure) and physiological (relating to organs and functions of the body) characteristics of the unborn child at the time the abortion is to be performed or induced.

2. Review of the facility's policy titled, "Patient Consent Policy," dated 06/18, showed:
- It is the policy of the Abortion Facility to comply with all applicable federal, state, and local laws and regulation in providing abortion care.
- The physician who will perform the abortion is required to provide the following information to a patient orally and in person at least seventy-two

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L1101	Continued From page 8 hours before the abortion procedure: * The unborn child's gestational age. (Note: The policy failed to specify the gestational age at the time of the abortion.) 3. Review of medical records showed: - The Seventy-two Hour Informed Consent was documented on 04/16/18 for Patient #1, #2, and #3 and the abortion was performed on 04/30/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 4/30/18 for Patient #4, #5, and #6 and the abortion was performed on 05/14/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 06/04/18 for Patient #8 and #9 and the abortion was performed on 06/18/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 05/14/18 for Patient #8 and the abortion was performed on 05/21/18, 7 days after the ultrasound was performed.. - The Seventy-two Hour Informed Consent was documented on 07/23/18 for Patient #10 and the abortion was performed on 07/30/18, 7 days after the ultrasound was performed. (Note: The gestational age presented to the pregnant woman at the time of the seventy-two hour consent visit was based on the determination of gestational age by ultrasound on that day and not the gestational age of the unborn child at the time of abortion.) 4. During an interview on 08/14/18 at approximately 1:30 PM, Staff B, Registered Nurse (RN), Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor), stated that:	L1101		

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L1101	Continued From page 9 - During the abortion education at the seventy-two hour informed consent visit the woman is given the gestational age of the embryo (a human offspring during the period from approximately the second to the eighth week after fertilization) based on her last menstrual period and told the gestational age would be confirmed by ultrasound. - The gestational age that is discussed is based on the ultrasound results at the time of the seventy-two hour visit, not the procedure date. - The day of procedure they go over gestational age again and discuss it but they do not use the Missouri Informed Consent Booklet or show them pictures of the gestational age of the unborn infant.	L1101		
L1119	19 CSR 30-30.060(3)(B) The facility shall maintain a medical record The facility shall maintain a medical record according to professional standards for each patient. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure discharge instructions were included in the medical record for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed:	L1119		

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L1119	Continued From page 10 - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 through 07/30/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained documentation of the discharge instructions provided to the patient. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - Discharge instructions were provided in the form of written instructions given to the patient: * "Surgical Abortion Discharge Instructions" including what was normal and what was abnormal, and staff contact numbers in the event of questions, concerns or an emergency; * "How Much Am I Bleeding," and * Instructions for taking prescribed medications. - The facility did not retain a copy of the instructions or include them in the medical record.	L1119		
L1120	19 CSR 30-30.060(3)(C) All medical record entries shall be timed All medical record entries shall be timed, dated, and signed or authenticated by the person making the entry.	L1120		

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L1120	Continued From page 11 This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure medication orders were timed, dated and signed by the ordering practitioner for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * II.J The medical record shall contain physician orders. All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry. (Note: The policy failed to address the need for medication orders, to be dated, timed and signed or authenticated by the person ordering the medications.) 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 for surgical abortion procedures showed the facility failed to ensure medication orders were signed, dated and timed by the ordering physician. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - She was aware the medication orders should	L1120		

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L1120	Continued From page 12 be timed, dated and signed by the physician when they were ordered. - The facility had developed a standard order set for medications but it had not been approved to be implemented.	L1120		
L1122	19 CSR 30-30.060(3)(D)(1) Documentation with a unique identifying recor Documentation with a unique identifying record number; patient identifying information; name of physician; diagnosis; medical history and physical examination record; laboratory reports; anesthesia administered; allergies/drug reactions; physician's orders; clinical notes; counseling notes; patient consent form; medication administration records; and discharge summary; This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that the physician documented the abortion counseling notes in the medical record for three (#3, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the facility's policy titled, "Medical Standards and Guidelines," dated 06/16 showed: - 1.2 Surgical Abortion: * 1.2.1 Patient Education and Informed Consent: All written materials given to the patient must be documented in record.	L1122		

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L1122	Continued From page 13 2. Review of the medical records for Patient #3, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 showed the records did not contain the physician counseling notes. 3. During an interview on 04/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The physician was responsible for documenting the abortion counseling that was performed during the initial patient visit in the medical record. - The medical records for Patients #3, #9, and #10 did not contain the required abortion counseling documentation.	L1122		
L1124	19 CSR 30-30.060(3)(D)(3) Method used to determine gestational age Method used to determine gestational age; gestational age; informed consent checklist required by section 188.027.3, RSMo; copy of abortion report required by section 188.052, RSMo, and 19 CSR 10-15.010; for surgical abortions, copy of tissue report required by section 188.047, RSMo, and 19 CSR 10-15.030; where applicable, copy of complication report required by section 188.052, RSMo, and 19 CSR 10-15.020; and This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure a copy of the abortion report was included in the medical record for two (#4 and #6) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases.	L1124		

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L1124	Continued From page 14 Findings included: 1. Review of Missouri law 188.052 RSMo, showed: - 1. An individual abortion report for each abortion performed or induced upon a woman shall be completed by her attending physician. - 4. A copy of the abortion report shall be made a part of the medical record of the patient of the facility or hospital in which the abortion was performed. 2. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 3. Review of the medical records for Patient #4, and #6 with an admission date of 05/14/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained a copy of the abortion report. 4. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The medical records for Patient #4 and #6 did not contain an abortion report. - Facility staff had failed to ensure a copy of the abortion report was included in the medical records for Patient #4 and #6.	L1124		

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L1130	Continued From page 15	L1130		
L1130	19 CSR 30-30.060(4) Infection Control Program Infection Control Program. The facility shall establish a comprehensive program for identifying and preventing infections. The infection control program shall be appropriate for scope and type of abortion procedures performed at the facility. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to ensure staff followed acceptable standards of practice for hand hygiene. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 2. Review of the Association for Professionals in	L1130		

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L1130	Continued From page 16 Infection Control and Epidemiology (APIC) scientific guidelines referred to in the CDC Morbidity and Mortality Weekly Report titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed the following: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 3. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Hand Hygiene," dated 2017, showed: - Recommendation I.d.4. * In the absence of visible soil, hands should be disinfected with an alcohol-based hand rub rather than washed with soap and water. - Recommendation III. * Perioperative team members should perform hand hygiene. - Recommendation III.a. * Personnel should perform hand hygiene: Before and after patient contact; Before performing a clean or sterile task; After risk for blood or body fluid exposure; After contact with patient surroundings; and When hands are visibly soiled. - Recommendation III.a.1. * Hand hygiene should be performed before and after patient contact, including:	L1130		

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L1130	Continued From page 17 Performing a physical exam; Marking the site; Transferring or positioning the patient; Assessing an invasive device (e.g., vascular catheter [peripheral, arterial, central], urinary catheter); and Assessing wound dressing. - Recommendation III.a.2. * Hand hygiene should be performed before a clean or sterile task, including: Inserting an invasive device (e.g., vascular catheter [peripheral, arterial, central] urinary catheter); Assessing a vascular device (e.g., port, stopcock, IV tubing); Moving from a contaminated body site (e.g., perineum) to a clean body site (e.g., face) on the same patient; Opening sterile supplies; and Performing patient skin antisepsis. - Recommendation III.a.3. * Hand hygiene should be performed after risk for blood or body fluid exposure, including: Removing personal protective equipment (e.g., gloves, mask); Having contact with blood, body fluids, excretions, mucous membranes, non-intact skin, or wound dressings; - Recommendation III.a.4. * Hand hygiene should be performed after contact with patient surroundings, including: Inanimate surfaces and objects, including medical equipment, in the immediate vicinity of the patient; Operating room (OR) bed controls; and Patient bed and linens. - Recommendation III.a.5. * The use of gloves does not replace the need for hand hygiene.	L1130		

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L1130	Continued From page 18 - Recommendation III.d. * When hands are not visibly soiled or dirty, hand hygiene should be performed using an alcohol-based hand rub according to the manufacturer's instructions for use. 4. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - CDC; - APIC; and - AORN. 5. Review of the facility's "Infection Prevention Manual" policy titled, "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE)," dated 08/15, showed: - Hand hygiene should be performed when hands are visibly soiled with blood or other body fluids, wash hands with water and soap. Wash hands even prior to donning gloves. - If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under "hand hygiene" above. 6. Observation on 08/13/18 from approximately 10:12 AM to 10:30 AM of Patient #11's abortion procedure showed Staff BB, Physician: - Entered the room, donned gloves and performed a manual vaginal exam; - Changed her gloves, did not perform hand hygiene, and performed a speculum (medical tool inserted into the vagina to dilate it for examination of the vagina and cervix) exam; - Picked up a bottle of spray vinegar solution and sprayed the solution in the patient's vaginal area; - Picked up a syringe of Lidocaine (numbing	L1130		

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L1130	Continued From page 19	L1130		

medication) and injected it into the patient's vaginal/cervix area;
- Disposed of the medication syringe, removed her soiled gloves, and donned sterile gloves without performing hand hygiene;
- Completed the abortion, cleansed the patient's vaginal area, removed her bloody gloves, failed to perform hand hygiene, and donned nonsterile gloves;
- Exited the room; and
- Carried the product of conception to the soiled area, examined the product of conception, removed her gloves, and performed hand hygiene.

7. Observation on 08/13/18 from approximately 11:10 AM to 11:35 AM of Patient #12's procedure showed Staff BB, Physician:
- Entered the room, examined the patient's medical record and donned a single glove, she failed to perform hand hygiene before donning the glove;
- Performed an abdominal ultrasound (test that uses sound waves to make images within the abdomen to determine the size/age of the fetus) on the patient, removed the glove, and failed to perform hand hygiene;
- Wiped the ultrasound gel off the patient's abdomen and had the patient sign paperwork; and
- Picked up the patient's medical record, reviewed the consent with the patient, had the patient sign the consent, Staff BB signed the consent, and exited the room without performing hand hygiene.

8. Observation on 08/13/18 from approximately 11:53 AM to 12:05 PM of Patient #13's lab visit for blood and urine testing showed Staff F,

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L1130	Continued From page 20 Licensed Practical Nurse: - Performed hand hygiene and donned gloves, moved a urine specimen cup from the wall cabinet to the sink, removed her gloves, and donned clean gloves. She failed to perform hand hygiene between gloves changes; - Tested the urine, removed her gloves and performed hand hygiene and documented in the medical record; and - Donned clean gloves without performing hand hygiene, obtained a blood sample, checked the blood sample and removed her gloves. She failed to perform hand hygiene after removing her gloves. 9. Observation on 08/13/18 at 2:00 PM showed: - Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) performed hand hygiene upon entering the room, obtained lab supplies to obtained a blood specimen; - Donned gloves, failed to perform hand hygiene prior to donning the gloves; - Drew blood from Patient #13, removed her gloves, failed to perform hand hygiene; - Escorted the patient to the door; and - Took the patient's medical record to the lab.	L1130		

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 08/13/18 to 08/14/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L1081	19 CSR 30-30.060(1)(B)(3) The administrator shall be responsible, plan The administrator shall be responsible for developing a written plan for evacuation of patients and personnel in the event of fire, explosion, active shooter, or other disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. Disaster drills with participation of all staff shall be conducted and documented at least annually. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that all staff participated in drills and were knowledgeable about the plan. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's document titled, "Quarterly Fire Drill Report," dated 02/18/18, showed that the facility had a fire drill on that date. The previous fire drill was held on 04/05/17. 2. During an interview on 08/14/18 at 2:33 PM,	L1081		

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L1081	Continued From page 1 Staff C, Health Center Manager, stated that: - She had been employed at the facility since March. - She had not participated in a fire drill or emergency drill since starting at the facility. - The facility was to have fire drills or emergency drills twice per year. 3. During an interview on 08/14/18 at 2:50 PM, Staff F, Licensed Practical Nurse, stated that: - She was from a staffing agency but worked full time hours at the facility and had done so since 07/19/18. - She had not participated in a fire or emergency drill since starting at the facility. - When asked if she knew where the designated safe spot during a tornado was she replied she did not know. - When asked if she knew how to activate the fire alarm she stated she did not know.	L1081		
L1084	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the	L1084		

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L1084	Continued From page 2 exam rooms; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. - Recommendation II.b. * All horizontal surfaces in the operating room (OR) (e.g., furniture, surgical lights, booms, equipment) should be damp dusted before the first scheduled surgical or other invasive procedure of the day. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. 2. Review of the facility's "Infection Prevention	L1084		

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L1084	Continued From page 3 Manual," dated 08/15, showed infection control resources included: - Centers for Disease Control (CDC); - Association for Professionals in Infection Control and Epidemiology (APIC); and - AORN. 3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed: - Thoroughly clean all surfaces that are used in patient care areas. - Avoid cleaning methods and machines that re-suspend dust from surfaces, especially in patient care areas. - All areas of the clinic should be kept clean and free from excess clutter. - The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment. 4. Observation on 08/13/18 at 10:40 AM of the procedure room showed the metal suction machine cabinet had numerous rusted areas (uncleanable surface). During an interview on 08/14/18 at 1:25 PM, Staff C, Health Center Manager, stated that she had cleaned the metal suction cabinet and confirmed it was rusted. 5. Observation on 08/13/18 at 10:45 AM of the recovery room medication supply room showed: - A metal shelf unit with five pressed wood shelves, the shelves were dusty; - A pressed wood shelf leaning against the wall; - The floor under the shelf unit was dusty; and - There was a box containing 25 expired hCG Urine Cassette Cultures (urine pregnancy test)	L1084		

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L1084	Continued From page 4 expiration 03/18, on the floor behind the shelving unit. During an interview upon the observation, Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) stated that housekeeping staff did not have access to the room and confirmed that the urine pregnancy tests were expired. 6. Observation on 08/13/18 at 2:10 PM of exam room 1 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue which created a noncleanable surface; - Dust and debris and a brown stained area in the cabinet under the sink ; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; and - The gooseneck lamp had a dried peeling label and adhesive residue. 7. Observation on 08/13/18 at 2:15 PM of exam room 2 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue; - Dust and debris and a grayish black discolored area in the cabinet under the sink and an area where the base of the cabinet was peeling; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; - A plastic glove box holder had dust on the top	L1084		

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L1084	Continued From page 5 that left a visible mark when a finger was drawn through; and - The cabinet under the sink had peeling and/or missing laminate at the bottom outer corner. 8. Observation on 08/13/18 at 2:20 PM of exam room 3 showed the top edges of two picture frames were dusty. 9. During an interview on 08/13/18 at 2:25 PM, Staff C stated that: - The housekeeper did not go into the recovery room supply cabinet; - Peeling laminate could not be disinfected; and - They planned to purchase new tables for the exam rooms. 10. Observation on 08/13/18 at 2:30 PM of the soiled area showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue.	L1084		
L1090	19 CSR 30-30.060(1)(B)(7)(E) Provisions for licensed personnel to have cur Provisions for licensed personnel to have current cardiopulmonary (CPR) training so that at least one (1) licensed and trained personnel is at the facility at all times when patients are present for abortions; and This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that licensed personnel maintained current cardiopulmonary (CPR) training for one (B) of two licensed staff personnel records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four	L1090		

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L1090	Continued From page 6 procedures. Findings included: 1. Review of the facility's policy titled, "Personnel Files," dated 05/15, showed personnel information collected by the facility included first aid/CPR cards. 2. Review of Staff B, Registered Nurse (RN), Nurse Practitioner's (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) personnel file showed her CPR training had expired 04/20/18. 3. During an interview on 08/14/18 at 1:30 PM, Staff B stated that: - She was required to maintain current CPR. - She was not aware her CPR certification had expired.	L1090		
L1101	19 CSR 30-30.060(2)(B) Each patient shall be given all the informati Each patient shall be given all the information required by sections 188.027 and 188.039, RSMo, in the formats and timeframes required, by the type of professional required. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to ensure that the physician who was to perform or induce the abortion or a qualified professional as required by law (Section 188.027.1(1), RSMO, a physician, physician assistant, registered nurse, licensed practical nurse, psychologist, licensed professional counselor or licensed social worker licensed or registered and working under the	L1101		

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L1101	Continued From page 7 supervision of the physician performing or inducing the abortion) informed the woman of the gestational age of the fetus at the time of abortion for ten (#1, #2, #3, #4, #5, #6, #7 #8, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of Missouri law 188.027 RSMo, showed consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion: (1) The physician who is to perform or induce the abortion, a qualified professional, or the referring physician has informed the woman orally, reduced to writing, and in person, of the following: (f) The gestational age (term used during pregnancy to describe how far along the pregnancy is) of the unborn child at the time the abortion is to be performed or induced; and (g) The anatomical (relating to bodily structure) and physiological (relating to organs and functions of the body) characteristics of the unborn child at the time the abortion is to be performed or induced. 2. Review of the facility's policy titled, "Patient Consent Policy," dated 06/18, showed: - It is the policy of the Abortion Facility to comply with all applicable federal, state, and local laws and regulation in providing abortion care. - The physician who will perform the abortion is required to provide the following information to a patient orally and in person at least seventy-two	L1101		

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L1101	Continued From page 8 hours before the abortion procedure: * The unborn child's gestational age. (Note: The policy failed to specify the gestational age at the time of the abortion.) 3. Review of medical records showed: - The Seventy-two Hour Informed Consent was documented on 04/16/18 for Patient #1, #2, and #3 and the abortion was performed on 04/30/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 4/30/18 for Patient #4, #5, and #6 and the abortion was performed on 05/14/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 06/04/18 for Patient #8 and #9 and the abortion was performed on 06/18/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 05/14/18 for Patient #8 and the abortion was performed on 05/21/18, 7 days after the ultrasound was performed.. - The Seventy-two Hour Informed Consent was documented on 07/23/18 for Patient #10 and the abortion was performed on 07/30/18, 7 days after the ultrasound was performed. (Note: The gestational age presented to the pregnant woman at the time of the seventy-two hour consent visit was based on the determination of gestational age by ultrasound on that day and not the gestational age of the unborn child at the time of abortion.) 4. During an interview on 08/14/18 at approximately 1:30 PM, Staff B, Registered Nurse (RN), Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor), stated that:	L1101		

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L1101	Continued From page 9 - During the abortion education at the seventy-two hour informed consent visit the woman is given the gestational age of the embryo (a human offspring during the period from approximately the second to the eighth week after fertilization) based on her last menstrual period and told the gestational age would be confirmed by ultrasound. - The gestational age that is discussed is based on the ultrasound results at the time of the seventy-two hour visit, not the procedure date. - The day of procedure they go over gestational age again and discuss it but they do not use the Missouri Informed Consent Booklet or show them pictures of the gestational age of the unborn infant.	L1101		
L1119	19 CSR 30-30.060(3)(B) The facility shall maintain a medical record The facility shall maintain a medical record according to professional standards for each patient. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure discharge instructions were included in the medical record for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed:	L1119		

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L1119	Continued From page 10 - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 through 07/30/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained documentation of the discharge instructions provided to the patient. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - Discharge instructions were provided in the form of written instructions given to the patient: * "Surgical Abortion Discharge Instructions" including what was normal and what was abnormal, and staff contact numbers in the event of questions, concerns or an emergency; * "How Much Am I Bleeding," and * Instructions for taking prescribed medications. - The facility did not retain a copy of the instructions or include them in the medical record.	L1119		
L1120	19 CSR 30-30.060(3)(C) All medical record entries shall be timed All medical record entries shall be timed, dated, and signed or authenticated by the person making the entry.	L1120		

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L1120	Continued From page 11 This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure medication orders were timed, dated and signed by the ordering practitioner for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * II.J The medical record shall contain physician orders. All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry. (Note: The policy failed to address the need for medication orders, to be dated, timed and signed or authenticated by the person ordering the medications.) 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 for surgical abortion procedures showed the facility failed to ensure medication orders were signed, dated and timed by the ordering physician. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - She was aware the medication orders should	L1120		

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COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1120	Continued From page 12 be timed, dated and signed by the physician when they were ordered. - The facility had developed a standard order set for medications but it had not been approved to be implemented.	L1120		
L1122	19 CSR 30-30.060(3)(D)(1) Documentation with a unique identifying recor Documentation with a unique identifying record number; patient identifying information; name of physician; diagnosis; medical history and physical examination record; laboratory reports; anesthesia administered; allergies/drug reactions; physician's orders; clinical notes; counseling notes; patient consent form; medication administration records; and discharge summary; This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that the physician documented the abortion counseling notes in the medical record for three (#3, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the facility's policy titled, "Medical Standards and Guidelines," dated 06/16 showed: - 1.2 Surgical Abortion: * 1.2.1 Patient Education and Informed Consent: All written materials given to the patient must be documented in record.	L1122		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

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COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1122	Continued From page 13 2. Review of the medical records for Patient #3, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 showed the records did not contain the physician counseling notes. 3. During an interview on 04/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The physician was responsible for documenting the abortion counseling that was performed during the initial patient visit in the medical record. - The medical records for Patients #3, #9, and #10 did not contain the required abortion counseling documentation.	L1122		
L1124	19 CSR 30-30.060(3)(D)(3) Method used to determine gestational age Method used to determine gestational age; gestational age; informed consent checklist required by section 188.027.3, RSMo; copy of abortion report required by section 188.052, RSMo, and 19 CSR 10-15.010; for surgical abortions, copy of tissue report required by section 188.047, RSMo, and 19 CSR 10-15.030; where applicable, copy of complication report required by section 188.052, RSMo, and 19 CSR 10-15.020; and This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure a copy of the abortion report was included in the medical record for two (#4 and #6) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases.	L1124		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1124	Continued From page 14 Findings included: 1. Review of Missouri law 188.052 RSMo, showed: - 1. An individual abortion report for each abortion performed or induced upon a woman shall be completed by her attending physician. - 4. A copy of the abortion report shall be made a part of the medical record of the patient of the facility or hospital in which the abortion was performed. 2. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 3. Review of the medical records for Patient #4, and #6 with an admission date of 05/14/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained a copy of the abortion report. 4. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The medical records for Patient #4 and #6 did not contain an abortion report. - Facility staff had failed to ensure a copy of the abortion report was included in the medical records for Patient #4 and #6.	L1124		

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L1130	Continued From page 15	L1130		
L1130	19 CSR 30-30.060(4) Infection Control Program Infection Control Program. The facility shall establish a comprehensive program for identifying and preventing infections. The infection control program shall be appropriate for scope and type of abortion procedures performed at the facility. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to ensure staff followed acceptable standards of practice for hand hygiene. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 2. Review of the Association for Professionals in	L1130		

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L1130	Continued From page 16 Infection Control and Epidemiology (APIC) scientific guidelines referred to in the CDC Morbidity and Mortality Weekly Report titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed the following: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 3. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Hand Hygiene," dated 2017, showed: - Recommendation I.d.4. * In the absence of visible soil, hands should be disinfected with an alcohol-based hand rub rather than washed with soap and water. - Recommendation III. * Perioperative team members should perform hand hygiene. - Recommendation III.a. * Personnel should perform hand hygiene: Before and after patient contact; Before performing a clean or sterile task; After risk for blood or body fluid exposure; After contact with patient surroundings; and When hands are visibly soiled. - Recommendation III.a.1. * Hand hygiene should be performed before and after patient contact, including:	L1130		

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L1130	Continued From page 17 Performing a physical exam; Marking the site; Transferring or positioning the patient; Assessing an invasive device (e.g., vascular catheter [peripheral, arterial, central], urinary catheter); and Assessing wound dressing. - Recommendation III.a.2. * Hand hygiene should be performed before a clean or sterile task, including: Inserting an invasive device (e.g., vascular catheter [peripheral, arterial, central] urinary catheter); Assessing a vascular device (e.g., port, stopcock, IV tubing); Moving from a contaminated body site (e.g., perineum) to a clean body site (e.g., face) on the same patient; Opening sterile supplies; and Performing patient skin antisepsis. - Recommendation III.a.3. * Hand hygiene should be performed after risk for blood or body fluid exposure, including: Removing personal protective equipment (e.g., gloves, mask); Having contact with blood, body fluids, excretions, mucous membranes, non-intact skin, or wound dressings; - Recommendation III.a.4. * Hand hygiene should be performed after contact with patient surroundings, including: Inanimate surfaces and objects, including medical equipment, in the immediate vicinity of the patient; Operating room (OR) bed controls; and Patient bed and linens. - Recommendation III.a.5. * The use of gloves does not replace the need for hand hygiene.	L1130		

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L1130	Continued From page 18 - Recommendation III.d. * When hands are not visibly soiled or dirty, hand hygiene should be performed using an alcohol-based hand rub according to the manufacturer's instructions for use. 4. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - CDC; - APIC; and - AORN. 5. Review of the facility's "Infection Prevention Manual" policy titled, "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE)," dated 08/15, showed: - Hand hygiene should be performed when hands are visibly soiled with blood or other body fluids, wash hands with water and soap. Wash hands even prior to donning gloves. - If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under "hand hygiene" above. 6. Observation on 08/13/18 from approximately 10:12 AM to 10:30 AM of Patient #11's abortion procedure showed Staff BB, Physician: - Entered the room, donned gloves and performed a manual vaginal exam; - Changed her gloves, did not perform hand hygiene, and performed a speculum (medical tool inserted into the vagina to dilate it for examination of the vagina and cervix) exam; - Picked up a bottle of spray vinegar solution and sprayed the solution in the patient's vaginal area; - Picked up a syringe of Lidocaine (numbing	L1130		

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L1130	Continued From page 19 medication) and injected it into the patient's vaginal/cervix area; - Disposed of the medication syringe, removed her soiled gloves, and donned sterile gloves without performing hand hygiene; - Completed the abortion, cleansed the patient's vaginal area, removed her bloody gloves, failed to perform hand hygiene, and donned nonsterile gloves; - Exited the room; and - Carried the product of conception to the soiled area, examined the product of conception, removed her gloves, and performed hand hygiene. 7. Observation on 08/13/18 from approximately 11:10 AM to 11:35 AM of Patient #12's procedure showed Staff BB, Physician: - Entered the room, examined the patient's medical record and donned a single glove, she failed to perform hand hygiene before donning the glove; - Performed an abdominal ultrasound (test that uses sound waves to make images within the abdomen to determine the size/age of the fetus) on the patient, removed the glove, and failed to perform hand hygiene; - Wiped the ultrasound gel off the patient's abdomen and had the patient sign paperwork; and - Picked up the patient's medical record, reviewed the consent with the patient, had the patient sign the consent, Staff BB signed the consent, and exited the room without performing hand hygiene. 8. Observation on 08/13/18 from approximately 11:53 AM to 12:05 PM of Patient #13's lab visit for blood and urine testing showed Staff F,	L1130		

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L1130	Continued From page 20 Licensed Practical Nurse: - Performed hand hygiene and donned gloves, moved a urine specimen cup from the wall cabinet to the sink, removed her gloves, and donned clean gloves. She failed to perform hand hygiene between gloves changes; - Tested the urine, removed her gloves and performed hand hygiene and documented in the medical record; and - Donned clean gloves without performing hand hygiene, obtained a blood sample, checked the blood sample and removed her gloves. She failed to perform hand hygiene after removing her gloves. 9. Observation on 08/13/18 at 2:00 PM showed: - Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) performed hand hygiene upon entering the room, obtained lab supplies to obtained a blood specimen; - Donned gloves, failed to perform hand hygiene prior to donning the gloves; - Drew blood from Patient #13, removed her gloves, failed to perform hand hygiene; - Escorted the patient to the door; and - Took the patient's medical record to the lab.	L1130		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 30, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains
711 N Providence Road
Columbia, MO 65203

RE: ***Licensure Survey TKOR11***

Dear Vicki Casey:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***August 14, 2018*** in connection with the ***State Licensure*** requirements as they pertain to abortion centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Enclosure

Americans United for Life

MO Bureau of Ambulatory Care —Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date (from CMS 2567)	8/14/2018
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	State or Federal SOD Q-tags, L-tags, K-tags, E-tags	

1. **Include a copy of the first page of each of the original forms CMS-2567** Statement(s) of Deficiencies for Federal (Q-tags, E-tags), State (L-tags) and Life Safety (K-tags) **signed & dated by administrator** or designee, along with associated completed POC forms **no later than ten (10) calendar days from receipt of this document**. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. Complete a **separate POC form for each applicable regulation set of the Statement of Deficiencies** (Federal Q-tags, E-tags, State L-tags, and Life Safety K-tags).

3. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation for Q-tags, E-tags, L-tags, and K-tags.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form CMS-2567 "Statement of Deficiencies" (Q181, L224, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date, and generally **must be** no later than 60 days from Exit. *(Limited extensions may be granted upon written request should extraordinary circumstances exist.)* To allow for adequate time for correction of deficiencies, should an onsite revisit be necessary, correction **should be completed** less than 45 days from Exit.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D." above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

Americans United for Life

MO Bureau of Ambulatory Care — Facility Plan of Correction (POC) Form

A (TAG)	**B (CORRECTIVE ACTION)**	**C (WHEN)**	**D (WHO)**	**E (EVIDENCE OF COMPLIANCE)**	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1081	CHPPGP will conduct future drills to include both part-time ("PRN") employees and temporary contractors, if applicable, to ensure that all employees who may be on-site when CHPPGP is operating the Columbia facility are prepared for evacuation during a disaster.	8/22/2018 (actions already completed) and 10/1/2018 (additional action item)	Health center manager and facility administrator	The manager has reviewed the current written plan for evacuation of patients and personnel in the event of a fire, explosion, active shooter or other disaster with Regional Director (facility administrator). Staff completed drills in preparation for emergencies on 8/21/2018 (active shooter training with third-party vendor) and 8/22/2018 (fire, tornado, and bomb threat) to ensure compliance. Because the active shooter training was provided by an outside party while CHPPGP's physician was not at the health center, an additional drill will be conducted while the physician is in attendance on or before October 1, 2018.	*See* Exhibit A (attached).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP will take the following steps in response to the items identified in this finding: 1. **Arrange an in-person meeting with its environmental services cleaning provider to review its expectations and standards.** Health center manager; regional director of health center operations (administrator); and vice president of operations, will attend the meeting and review with the environmental services provider each of the areas identified in DHSS's report. This step is designed to address the dust-related portions of the finding. 2. **Document on a log the daily inspection performed by personnel at the facility prior to seeing patients.** The log will be maintained for 30 days by manager and submitted to regional director for review. This step is designed to address the dust-related portions of the finding and to ensure that expired tests that are not intended for future use are disposed of in a timely manner.	Item 1 will occur within 30 days of the submission of this POC. Item 2 will commence on 10/15/18, be evaluated daily, and conclude on 11/14/18.	Vice president of operations Manager and administrator	Item 1, a one-time meeting, will be monitored by center manager and regional director of health services operations. Item 2 will be monitored on a daily basis by manager, and on a weekly basis by regional director of health services operations (administrator).	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	3. **Administrator and VP of Operations will review with CHPPGP's facilities coordinator the following issues:** 1) Rusted areas on cabinet in observation 4; shelf in observation 5; peeling label and adhesive on chart holder and lamp, debris and stain under sink, and chipped paint in observation 6; peeling label and adhesive, debris and mark under sink, peeling on base of cabinet, chipped paint on pressed wood, and chipped laminate in observation 7; and residue under sink in observation 10. The facilities coordinator will outline a process for repair and/or replacement for those items.	The meeting outlined in Item 3 will be concluded by 10/1/18, and repairs/replacements will be concluded by October 31, 2018.	Vice president of operations	Item 3 will be monitored by vice president for operations. In addition to scheduling the initial meeting, vice president for operations will oversee repairs and/or replacements, as necessary.	

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1090	CHPPGP objects to the deficiency in L1090, as at all times during which it operated in 2017-2018 at least one licensed employee with current CPR training was onsite, as required by regulation. CHPPGP provided to surveyors copies of CHPPGP personnel files for those employees involved in the provision of abortion care, and those files reflect current CPR training for multiple individuals.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1101	CHPPGP objects to the deficiency identified in L1101. Pursuant to state law, CHPPGP provides to patients required information at the time of their state-mandated first visit, which must occur at least 72 hours prior to the performance of an abortion procedure. CHPPGP also is required and does provide to patients Missouri's Informed Consent Booklet, which by statute must include "probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from conception to full term, including color photographs or images of the developing unborn child at two-week gestational increments." § 188.027(2), RSMo. That booklet, provided to each patient, fulfills this requirement as it outlines state-mandated descriptions of changes in gestational age from the date of a patient's first visit to her second visit. CHPPGP will ensure appropriate staff specifies during the first visit that, because of the state-mandated delay, the patient's pregnancy is anticipated to be at a certain point when she	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	returns, and the state-created description of the fetus at that future gestation is in the Missouri Informed Consent Booklet. If, for some reason, a patient needs to reschedule her appointment, the booklet will also contain the state-created description of the fetus for that later time.				

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1119	CHPPGP objects to the deficiency identified in L1119 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that each patient receiving abortion care is provided with discharge instructions that include the following hand-outs: 1) How Much Am I Bleeding? (describing post-procedure normal and abnormal bleeding); 2) medication instructions; and 3) and surgical abortion discharge instructions, which include the facility's after-hours telephone number. DHSS's report does not state, however, that an entry is made by CHPPGP personnel in each patient's medical record that the patient received copies of those documents. That entry satisfies the regulation's requirement that written discharge instructions be provided to patients.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1120	CHPPGP objects to the deficiency identified in L1120 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that the physician providing care signed and dated the visit summary generated by the electronic health record, which reflects the medications prescribed during the patient encounter. To CHPPGP's knowledge, DHSS has not prior to its 2018 inspections interpreted this regulation to require each separate portion of a patient's medical record be signed and authenticated by the treating physician. As CHPPGP noted during the on-site inspection, however, it created a hard copy form in response to the inspection at its Kansas City facility. This form will provide an additional place for the physician to sign, date, and time medication orders for each patient and will be scanned into the medical record. This entry will be duplicative of that information on the patient's visit summary.	*In progress*	Administrator	The form has already been developed and is in use. The center manager will review electronic health records for all patients receiving abortion care for one month after the form has been in use to monitor for compliance.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1122	CHPPGP objects to the deficiency identified in L1122 to the extent it misstates the nature of the information conveyed during the survey process. For each of the patient records reviewed by the surveyor, a physician or qualified health professional (as defined by § 188.027, RSMo) provided the state-mandated information to patients receiving abortion care. The records described in L1122 reflected that persons meeting the statutory and regulatory definitions gave the required information. CHPPGP's physician *elected* to note in a number of patient records that she had delivered state-mandated information; however, that notation was only intended to duplicate what the other records in each patient's record showed: that required personnel delivered the information. CHPPGP's physician simply went above and beyond by reiterating that she had followed state law. To the extent that notation creates confusion for DHSS, CHPPGP will note for its provider that the notation is not necessary.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1124	CHPPGP objects to the deficiency identified in L1122 *in part* to the extent it misstates the nature of the information conveyed during the survey process. At the time of inspection, two state-mandated reports, Induced Termination of Pregnancy (ITOP) reports, had already been submitted to DHSS as required but had not yet been scanned into the patients' electronic medical record. CHPPGP staff located both reports on the day of inspection, and they have since been scanned into the patients' electronic records. Additionally, CHPPGP has revised its indexing process. Administrative personnel continue to handle the submission of ITOP reports to DHSS, but the center manager now submits reports for each procedure by the close of business on the day the procedures were performed.	Completed 8/15/2018	Center manager and regional director (administrator)	Regional Director will be responsible for monitoring new process and verifying that all ITOP reports are submitted pursuant to revised procedure.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1130	The director of clinical quality risk management will conduct a comprehensive training with facility staff to serve as a refresher course on CHPPGP's infection control program. CHPPGP's health center manager will also perform quarterly audits to ensure ongoing compliance after the education session.	Training will be conducted by 9/30/2018	Director of clinical quality risk management and administrator	Regional director (administrator) will conduct unannounced audits after completion of training on a quarterly basis.	N/A

Emergency Drill Attendance
August 22, 2018
Fire, Tornado, Bomb Threat

[redacted] HCM

[redacted] Lead Office Assistant

[redacted] NP

[redacted] LPN

[redacted] LPN Temp

[redacted] Assistant VP of Health Services

[redacted] VP of Health Services

[redacted] Grassroots Organizer

[redacted] Lobbyist

Dr. [redacted]

[redacted] Security officer

[redacted]

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Bomb Threat Drill Report
Semi-Annual

Center: COLUMBIA Date: 8/22/18 Time of Threat: 12:20

Staff Receiving Threat: Drill

Staff Present: [redacted]

Yes	No	Staff receiving threat notified Center Manager/designee [redacted]
Yes	No	Bomb Threat instructions posted at phone
Yes	No	Phone guidelines followed and appropriate data recorded
Yes	No	Manager notified Security Director or next level supervision
Yes	No	Police/Fire Department notified
Yes	No	Control Center Established
Yes	No	Search area assignments made
Yes	No	NO light switches are disturbed
Yes	No	All areas checked per pre-determined checklist for the center
Yes	No	Suspicious item(s) found; item(s) not moved or touched
Yes	No	If yes, manager informed and decision made to evacuate/not evacuate

Discussed

Comments: Drill, no threat received

Staff: [redacted] Title: Health Center Manager

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Fire Drill Report
Semi-Annual

Center: COLUMBIA Date: 6/22/18 **Time Started:** 12:30 **Time Ended:** _____

STAFF PRESENT: [redacted]

Alarm Performance

How was drill initiated? Fire alarm pull station_____ Smoke Alarm_____ Verbal

Location of fire alarm station/smoke alarm used Pointed out

What technique was used to indicate fire? ~~Clock~~ 0

Drill Type: Audible alarm_____ Coded/silent alarm_____

Date alarm audibly tested (if not tested during the drill): 6/26/18

Did all staff hear the alarm? (Yes) No

Did all fire emergency equipment function properly? (Yes) No

What time did dispatch receive the alarm: 0

Personnel Performance

RESCUE

(Yes)	No	Were all the staff, patients and visitors evacuated from the fire zone?
(Yes)	No	Was the proper/systematic search conducted
(Yes)	No	Did staff account for all patients?
(Yes)	No	Duties Divided as needed

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ALARM

Who activated the alarm? Protection 1

Yes No Was the alarm properly activated?

Yes No Did staff call the fire department? but discussed

Yes No Was the alarm reset?

CONTAINMENT

Yes No Did staff close office doors?

Yes No Were corridor doors unobstructed?

Yes No Did all corridor doors latch properly?

EXTINGUISHMENT/EVACUATION

Yes No Were proper fire extinguishers taken to fire area?

Yes No Did staff simulate using a fire extinguisher?

Yes No Did staff stay with evacuated patients?

Yes No If a "large" fire, were evacuation plans followed?

Yes No How long did it take to secure/evacuate all areas?

Discussed

COMMENTS/SENERIO:

Staff: [redacted] Title: Health Center Manager

Americans United for Life

Tornado Drill Report
Semi-Annual

Center: COLUMBIA Date: 8/22/18 Time Started: 12:10 Time Ended: _____

Staff Present: [redacted]

Number of Patients: 0

Yes No Were patients and staff moved to an area designated as safe?

Yes No Radio on and turned to station providing the weather

Yes No Staff hearing alert notified Center Manager or assumed responsibility

Yes No Duties Divided as needed

Yes No Staff assured all patients informed/moved and instruction were given

Yes No All staff knew designated areas. (Bathrooms, store room, break room, etc.)

Yes No All patient records secure

Yes No All cash receipts and cash secure

Yes No Emergency lights and equipment were available, accessible, and operational

Flashlights Emergency lighting Blankets First aid kit

Yes No Need for medical care assessed

Yes No Damage to building assessed and action taken to assure no other danger present

Comments: Drill, no threat received

Staff: [redacted] Title: Health Center Manager

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REMOVE STUB - SEPARATE FORMS BEFORE FILLING OUT

[redacted]

FIRE INSPECTION AND TESTING REPORT

Customer Number [redacted] Telephone Number [redacted] Branch Number ____ Contract Number ____

CS Number [redacted] Site Number ____ Job Number [redacted]

Customer Last Name Planned Parenthood First Name ____ MI ____ Today's Date ____

Site Address 711 N Providence City Columbia State MO Zip Code 65203

Billing Address (if different from above) ____ City ____ State ____ Zip Code ____

TYPE TRANSMISSION
- McCulloh
- Multiplex
- Digital
- Reverse Priority
- RF
- Other (Specify) [redacted]

Control Unit Manufact. [redacted]
Circuit Styles:
Number of Circuits:
Software Rev.:

SERVICE
- Weekly
- Monthly
- Quarterly
- Semiannually
- Annually
- Other (Specify) ____

Model No.: ____

Last Date System Had Any Service Performed: ____
Last Date That Any Software or Configuration Was Revised: ____

ALARM-INITIATING DEVICES AND CIRCUIT INFORMATION

Quantity of Devices Installed	Circuit Style	Quantity of Devices Tested	
3	B	1	Manual Fire Alarm Boxes
12	B	2	Ion Detectors
1	B		Photo Detectors
1	Serial	1	Duct Detectors
1	Serial		Heat Detectors
			Waterflow Switches
			Supervisory Switches
			Other (Specify): ____

Alarm verification feature is [redacted]

ALARM NOTIFICATION APPLIANCES AND CIRCUIT INFORMATION

Quantity of Appliances Installed	Circuit Style	Quantity of Appliances Tested	
9	B		Bells
9	B		Horns
			Chimes
			Strobes
			Speakers
			Other (Specify): ____

No. of alarm notification appliance circuits: ____
Are circuits monitored for integrity? ☐ Yes ☐ No

SUPERVISORY SIGNAL-INITIATING DEVICES AND CIRCUIT INFORMATION

Quantity of Devices Installed	Circuit Style	Quantity of Devices Tested	
			Building Temp.
			Site Water Temp.
			Site Water Level
			Fire Pump Power
			Fire Pump Running
			Fire Pump Auto Position
			Fire Pump or Pump Controller Trouble
			Fire Pump Running
			Generator in Auto Position
			Generator or Controller Trouble
			Switch Transfer
			Generator Engine Running
			Other: ____

SIGNALING LINE CIRCUITS
Quantity and style of signaling line circuits connected to system *(see NFPA 72, Table 6.6.1)*:
Quantity 2 Style(s) POTS + Cell

SYSTEM POWER SUPPLIES
(a) Primary (Main): Nominal Voltage [redacted]
Overcurrent Protection: Type ____
Location (of Primary Supply Panelbo
Disconnecting Means Location:
(b) Secondary (Standby):
Calculated capacity in
Engine-driven generator dedicated to fire alarm system?
Location of fuel storage:

TYPE BATTERY
- Dry Cell
- Lead-Acid
- Other (Specify):

[redacted]

ndby system used as a backup to primary power supply, instead of using a secondary pow
mergency system described in NFPA 70, Article 700
egally required standby described in NFPA 70, Article 701
ptional standby system described in NFPA 70, Article 702, which also meets the performance

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REMOVE STUB - SEPARATE FORMS BEFORE FILLING OUT

PRIOR TO ANY TESTING

NOTIFICATIONS ARE MADE	Yes	No	
Monitoring Entity			[redacted]
Building Occupants			
Building Management			
Other (Specify)			
AHJ Notified of Any Impairments			

SYSTEM TESTS AND INSPECTIONS

TYPE	Visual	Functional	Comments
Control Unit	✓	✓	
Interface Equipment	✓	✓	
Lamps/LEDs	✓	✓	
Fuses	✓	✓	
Primary Power Supply			
Trouble Signals	✓	✓	
Disconnect Switches			
Ground-Fault Monitoring			

SECONDARY POWER TYPE	Visual	Functional	Comments
Battery Condition	✓	✓	
Load Voltage			
Discharge Test			
Charger Test			
Specific Gravity			
TRANSIENT SUPPRESSORS			
REMOTE ANNUNCIATORS			
NOTIFICATION APPLIANCES			
Audible	✓	✓	
Visible	✓	✓	
Speakers			
Voice Clarity			

INITIATING AND SUPERVISORY DEVICE TESTS AND INSPECTIONS

[redacted]

Device Type	Visual Check	Functional Test	Factory Setting	Measured Setting	Pass	Fail
Smoke Det	✓	✓			✓	
Pull ST	✓	✓			✓	
SE Sprinkler Rm	✓	✓			✓	
Smoke	✓	✓			✓	

Comments:

EMERGENCY COMMUNICATIONS EQUIPMENT	Visual	Functional	Comments
Phone Set	✓	✓	
Phone Jacks			
Off-Hook Indicator	✓	✓	
Amplifier(s)			
Tone Generator(s)			
Call-In Signal	✓	✓	
System Performance			

COMBINATION SYSTEMS	Visual	Device Operation	Simulated Operation
Fire Extinguisher Monitoring Device/System			
Carbon Monoxide Detector/System			
(Specify)			
INTERFACE EQUIPMENT			
(Specify)			
(Specify)			
(Specify)			
SPECIAL HAZARD SYSTEMS			
(Specify)			
(Specify)			
(Specify)			

Special Procedures:

Comments:

SUPERVISING STATION MONITORING	Yes	No	Time	Comments
Alarm Signal	✓			
Alarm Restoration				
Trouble Signal	✓			
Trouble Signal Restoration				
Supervisory Signal				
Supervisory Restoration				

NOTIFICATIONS THAT TESTING IS COMPLETE	Yes	No		Time
Building Management			[redacted]	
Monitoring Agency				
Building Occupants				
Other (Specify)				

The following did not operate correctly:

System restored to normal operation: Date _____ Time: _____

THIS TEST
Name of In
Signature:
Name of O [redacted]

C Facility - Exhibit A
Page 007

Americans United for Life

Active Shooter Training 8/21/18

[redacted]

From: [redacted]
Sent: Wednesday, August 22, 2018 1:35 PM
To: [redacted]
Subject: Re: Thank you!

Good afternoon,
Thanks for completing the active assailant training on 8-21-18. If you need any other training feel free to get in touch.

Thank
[redacted]

Sent from my iPhone

On Aug 22, 2018, at 1:26 PM, [redacted] wrote:

Hi [redacted]

We just wanted to say thank you for coming to do active assailant training with us here at the Columbia Planned Parenthood. If you wouldn't mind sending us something stating we completed your training for our records, that would be great!

Thanks Again!

In Attendence

[redacted] HCN
[redacted] Lead Front office
[redacted] NP
[redacted] Temp LPN
[redacted] LPN
Grassroots Org.

[redacted]
Health Center Manager II
[redacted]

www.PPGreatPlains.org
<image001.png>

PP Great Plains works to ensure that every individual has the knowledge opportunity and freedom to make informed, private decisions about reproductive and sexual health.

<=”” img=”” src=”cid:”>

Planned Parenthood®
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Comprehensive Health of
Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 7, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

Enclosed please find the responses and plans of correction from Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP") to DHSS's statements of deficiency regarding CHPPGP's Columbia abortion facility. As part of its response, CHPPGP has included the following enclosures:

1. A signed copy of the Statement of Deficiency forms provided by DHSS. The facility administrator of CHPPGP's Columbia facility, Vicki Casey, has signed each page of the DHSS forms that appear to be largely modeled on CMS Form 2567.

2. Separate pages for each Plan of Correction and/or Objections.

CHPPGP strives to provide the highest quality care; however, many of the findings and requirements imposed by the State of Missouri and the Department of Health and Senior Services are not medically necessary and do not enhance patient outcomes. They also are, on their face, in contradiction with established United States Supreme Court precedent and are not in alignment with American College of Obstetricians and Gynecologists standards. CHPPGP notes that any agreement contained in its plans of correction to abide by federal or state laws or regulations is subject to those requirements being in force. If at any time those requirements are enjoined, modified, or otherwise rendered to have no effect, CHPPGP's plans of correction do not constitute voluntary agreement to comply with the stated requirements.

CHPPGP looks forward to working with DHSS to resolve those findings identified by the department during its recent inspection.

Sincerely,

Brie K. Anderson

Brie Anderson
Vice President for Health Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711
Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

October 16, 2018

Emily Wales
Chief Compliance Officer and General Counsel
Comprehensive Health of Planned Parenthood Great Plains
4402 W 109th St. #100
Overland Park, KS 66211

Dear Ms. Wales:

In accordance with 19 CSR 30-30.070(2), the Missouri Department of Health and Senior Services, Section for Health Standards and Licensure (DHSS), has approved your request to deviate from the requirements of regulation 19 CSR 30-30.070(3)(N) as set forth below for Comprehensive Health of Planned Parenthood Great Plains, 711 N. Providence Road, Columbia, MO 65203 (CHPPGP).

CHPPGP shall meet the clear space requirement of the regulation by maintaining three (3) recovery beds or recliners rather than four (4). Maintaining only three (3) recovery beds or recliners in the space available will allow space for emergency response personnel to access patients if necessary. This deviation is conditioned upon CHPPGP scheduling appointments in a manner that ensures that at no time more than three (3) patients are in simultaneous need of recovery.

This deviation shall not take effect until after CHPPGP has submitted an acceptable plan of correction for the statement of deficiencies issued September 28, 2018, and DHSS has approved the plan of correction and confirmed that such deficiencies have been corrected. The effective date of the deviation shall be the date that a license, if any, is issued. CHPPGP cannot be licensed unless it meets the hospital privileges requirement.

The deviation shall remain in effect until there is a change in circumstances, CHPPGP fails to comply with the requirements herein, or DHSS determines that there is a detrimental impact on the health, safety, or welfare of the patients, staff or public.

Abortions shall not be performed at CHPPGP until the facility is licensed and in compliance with all applicable laws, including but not limited to the hospital privileges requirement (Section 188.080, RSMo).

CHPPGP shall submit a copy of this deviation letter with its annual licensure renewal. If you have questions regarding this correspondence, please contact me at (573) 526-1864.

Sincerely,

William Koebel
Section Administrator
Section for Health Standards and Licensure

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Comprehensive Health of
Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 12, 2018

Via U.S. mail and email to: William.Koebel@health.mo.gov

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: *Request for Deviation*

Dear Mr. Koebel:

As you are aware, in 2007, the Missouri Legislature amended the Ambulatory Surgical Center Licensing Law to require any facility performing five or more first trimester abortions or one or more second trimester abortions be licensed as an ambulatory surgical center. Following that change, the Department refused to license Comprehensive Health of Planned Parenthood Great Plains' (CHPPGP) Columbia health center (as well as its Kansas City facility). After CHPPGP sued and obtained a preliminary injunction, the Department entered into a settlement agreement in 2010 by which it would license the Columbia health center to provide both medication and surgical abortion, based on CHPPGP's making certain agreed-upon changes to the health center.

Subsequent to that settlement agreement, the Department for the first time in 2015 advised CHPPGP that it would need to seek a waiver to provide abortions without having four recliners with at least three feet of clear space on both sides and at the foot of each recliner in its recovery room, as required by 19 CSR 30-30.070(3)(N). The Department did not require such waiver previously, even though the health center offered both medication and surgical abortion following the 2010 settlement agreement. CHPPGP duly applied for the waiver, and recognizing no threat to patient health or safety, the Department granted that waiver application and licensed the Columbia health center to provide medication abortion.

However, following an onsite survey conducted on October 11, 2016, the Department determined the Columbia health center was not in compliance with the above regulation because, according to the November 2, 2016 survey results, the previously approved variance did not extend to surgical abortion. The 2016 survey results also found the Columbia center was not in compliance with 19 CSR 30-30.070(3)(X), because the patient lavatory was not equipped with a constant running exhaust (despite that this same exhaust system had been approved repeatedly in the past, most recently in 2015).

As you also know, the physical facility requirements in 19 CSR 30-30.070 have been preliminarily enjoined since May 2, 2017. Given the Eighth Circuit's recent decision vacating that preliminary injunction, CHPPGP now seeks a waiver from 19 CSR 30-30.070(3)(N) for its Columbia health center, pursuant to 19 CSR 30-30.070(2). The physical standards regulation requires that the "recovery room . . . shall be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner." 19 CSR 30-30.070(3)(N).

The Columbia facility cannot fit four recliners with at least three feet of clear space on both sides and at the foot of each recliner; it can only fit three recliners with these clearances. Creating additional space is not feasible, as it would require (a) demolishing and relocating existing walls, both of which border restroom facilities, and (b) taking square footage away from the adjoining procedure room and/or personnel change room, neither of which is permitted by the terms of the 2010 settlement agreement.

The current configuration of four recliners is appropriate to protect patient health and safety, and there would be no health or safety benefit to removing one recliner in order to allow greater clearances. The lack of an incision, general anesthesia, and deep or moderate sedation means that most patients require only minimal duration of recovery following a surgical abortion. Indeed, because the Columbia health center provides only minimal sedation (valium and a topical anesthetic) at present, patients typically require less than 20-30 minutes of recovery. Current clearances allow appropriate patient monitoring during this recovery. Indeed, during the recent inspection of the Columbia facility, on August 13 and 14, 2018, the Department did not express any concerns about the current configuration of our four recliners.

We, therefore, request a waiver of the requirement for three feet of clear space at the sides and foot of each recliner, or in the alternative, the requirement to have four recliners for each procedure room. Because of the short duration of recovery following a surgical abortion, three recliners is sufficient to meet our patients' needs. CHPPGP will resolve the exhaust fan issue by September 21, 2018.

To avoid an interruption of services, **CHPPGP respectfully requests a written response to this request by September 18**. CHPPGP is aware that the Department is unable to waive the hospital-privileges requirements and intends to seek another preliminary injunction against those provisions so that it can continue to provide services uninterrupted after the Eighth Circuit's mandate issues.

Should the Department take the position that it would need to re-inspect the Columbia facility, please advise us promptly. If the Department requires an abortion-providing physician to be present for any such inspection, our physician will be at the health center on September 17 and 21. Following September 21, CHPPGP next has abortion patients scheduled on October 3, but inspection at this time will cause a lapse in services, given that our license expires on October 2. In order to avoid such an interruption, we expect the Department to process this request, as well as our license

reapplication, in good faith and ahead of the license's expiration date, so that there is no interruption of services.

Finally, as I informed Ms. Loethen in response to your call on September 10 advising CHPPGP to cease "immediately" all abortion services because its physician does not have the required hospital privileges, CHPPGP will continue to provide abortion services to its patients, as allowed by the preliminary injunction, until the Eighth Circuit's mandate issues pursuant to the Federal Rules of Appellate Procedures, which would happen at the earliest on October 1.

I look forward to hearing your prompt response to this request.

Sincerely,

Emily Wales
Chief Compliance Officer & General Counsel

CC:

Nikki Loethen, General Counsel, Department of Health and Senior Services
D. John Sauer, First Assistant and Solicitor, Attorney General's Office

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

September 13, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains, Inc
711 N Providence Road
Columbia, MO 65203

RE: ***PoC Rejection TKOR***

Dear Vicki Casey:

On September 10, 2018 our Bureau received your Plan of Correction as a result of a Licensure Survey Survey conducted August 14, 2018. Your Plan of Correction is unacceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

The facility has requested that the license not be allowed to lapse. To help ensure that, would the facility be able to implement any of the corrective actions sooner than the dates listed for tags L1084 and L1130?

L-1119 How will the facility ensure a copy of the discharge instructions will be included in the patient's medical record, consistent with current standards for medical record keeping.

L-1120 On what date does the facility expect the physician order document to be approved and implemented as the response only states in process.

L-1124 At the time of survey the state mandated reports were not included in two of the ten medical records reviewed and were not submitted to the survey team as available for the medical record. Going forward, how will the facility ensure the state mandated reports are included in the patients' medical record.

For 1130: Does the hand hygiene/glove use training include the physician?

Please submit a revised Plan of Correction with the above mentioned information within five (5) calendar days from the receipt of this notice via email to BAC@health.mo.gov or fax to (573) 751-6648 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Planned Parenthood®
Care. No matter what.
Comprehensive Health of
Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 20, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

As requested by DHSS surveyors during the re-inspection of the Kansas City facility operated by Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP"), CHPPGP has provided a number of updates and revised deadlines for the corrective action plans for its Columbia facility. Although all of CHPPGP's initial deadlines met the 45-day requirement laid out in the Department's plan of correction form (except for ongoing monitoring or audits, of course), CHPPGP has already completed many of its action items and is willing to move forward quickly to resolve any findings.

As you'll see in the attached response, all updates or revisions have been highlighted, so DHSS can easily identify where changes have been made. We anticipate that all necessary tasks – again, excluding ongoing monitoring or audit work – will be completed prior to next Friday, September 28, 2018.

We appreciate your notifying us during your Kansas City visit that revised deadlines would assist with a timely resolution of any alleged findings identified by the Department. Our goal, as always, is to provide high quality care that patients are able to access without any interruption in services.

Sincerely,

Brie Anderson
Vice President for Health Services

Americans United for Life

MO Bureau of Ambulatory Care —Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date (from CMS 2567)	8/14/2018
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	State or Federal SOD Q-tags, L-tags, K-tags, E-tags	

1. **Include a copy of the first page of each of the original forms CMS-2567** Statement(s) of Deficiencies for Federal (Q-tags, E-tags), State (L-tags) and Life Safety (K-tags) **signed & dated by administrator** or designee, along with associated completed POC forms **no later than ten (10) calendar days from receipt of this document**. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. Complete a **separate POC form for each applicable regulation set of the Statement of Deficiencies** (Federal Q-tags, E-tags, State L-tags, and Life Safety K-tags).

3. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation for Q-tags, E-tags, L-tags, and K-tags.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form CMS-2567 "Statement of Deficiencies" (Q181, L224, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date, and generally **must be** no later than 60 days from Exit. *(Limited extensions may be granted upon written request should extraordinary circumstances exist.)* To allow for adequate time for correction of deficiencies, should an onsite revisit be necessary, correction **should be completed** less than 45 days from Exit.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D." above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

Americans United for Life

MO Bureau of Ambulatory Care — Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1081	CHPPGP will conduct future drills to include both part-time ("PRN") employees and temporary contractors, if applicable, to ensure that all employees who may be on-site when CHPPGP is operating the Columbia facility are prepared for evacuation during a disaster.	8/22/2018 (actions already completed) and 10/1/2018 (additional action item) UPDATE: All action items were completed by 8/22/2018. The only outstanding item will be completed on the morning of 9/21/2018.	Health center manager and facility administrator	The manager has reviewed the current written plan for evacuation of patients and personnel in the event of a fire, explosion, active shooter or other disaster with Regional Director (facility administrator). Staff completed drills in preparation for emergencies on 8/21/2018 (active shooter training with third-party vendor) and 8/22/2018 (fire, tornado, and bomb threat) to ensure compliance. Because the active shooter training was provided by an outside party while CHPPGP's physician was not at the health center, an additional drill will be conducted while the physician is in attendance on or before October 1, 2018.	*See* Exhibit A (attached).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
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L1084	CHPPGP will take the following steps in response to the items identified in this finding: 1. **Arrange an in-person meeting with its environmental services cleaning provider to review its expectations and standards.** Health center manager; regional director of health center operations (administrator); and vice president of operations, will attend the meeting and review with the environmental services provider each of the areas identified in DHSS's report. This step is designed to address the dust-related portions of the finding. 2. **Document on a log the daily inspection performed by personnel at the facility prior to seeing patients.** The log will be maintained for 30 days by manager and submitted to regional director for review. This step is designed to address the dust-related portions of the finding and to ensure that expired tests that are not intended for future use are disposed of in a timely manner.	Item 1 will occur within 30 days of the submission of this POC. UPDATE: An initial meeting between the manager the provider has already been conducted. Another meeting is scheduled to be completed on September 21, 2018. Item 2 will commence on 10/15/18, be evaluated daily, and conclude on 11/14/18.	Vice president of operations Manager and administrator	Item 1, a one-time meeting, will be monitored by center manager and regional director of health services operations. Item 2 will be monitored on a daily basis by manager, and on a weekly basis by regional director of health services operations (administrator).	N/A

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	3. **Administrator and VP of Operations will review with CHPPGP's facilities coordinator the following issues:** 1) Rusted areas on cabinet in observation 4; shelf in observation 5; peeling label and adhesive on chart holder and lamp, debris and stain under sink, and chipped paint in observation 6; peeling label and adhesive, debris and mark under sink, peeling on base of cabinet, chipped paint on pressed wood, and chipped laminate in observation 7; and residue under sink in observation 10. The facilities coordinator will outline a process for repair and/or replacement for those items.	UPDATE: Item 2 will commence as soon as the second meeting with the provider occurs. The meeting outlined in Item 3 will be concluded by 10/1/18, and repairs/replacements will be concluded by October 31, 2018. UPDATE: All actions outlined in Item 3 have been performed except for one outstanding repair. That work is scheduled to be completed on or before September 25, 2018.	Vice president of operations	Item 3 will be monitored by vice president for operations. In addition to scheduling the initial meeting, vice president for operations will oversee repairs and/or replacements, as necessary.	

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L1090	CHPPGP objects to the deficiency in L1090, as at all times during which it operated in 2017-2018 at least one licensed employee with current CPR training was onsite, as required by regulation. CHPPGP provided to surveyors copies of CHPPGP personnel files for those employees involved in the provision of abortion care, and those files reflect current CPR training for multiple individuals.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1101	CHPPGP objects to the deficiency identified in L1101. Pursuant to state law, CHPPGP provides to patients required information at the time of their state-mandated first visit, which must occur at least 72 hours prior to the performance of an abortion procedure. CHPPGP also is required and does provide to patients Missouri's Informed Consent Booklet, which by statute must include "probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from conception to full term, including color photographs or images of the developing unborn child at two-week gestational increments." § 188.027(2), RSMo. That booklet, provided to each patient, fulfills this requirement as it outlines state-mandated descriptions of changes in gestational age from the date of a patient's first visit to her second visit. CHPPGP will ensure appropriate staff specifies during the first visit that, because of the state-mandated delay, the patient's pregnancy is anticipated to be at a certain point when she	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	returns, and the state-created description of the fetus at that future gestation is in the Missouri Informed Consent Booklet. If, for some reason, a patient needs to reschedule her appointment, the booklet will also contain the state-created description of the fetus for that later time.				

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1119	CHPPGP objects to the deficiency identified in L1119 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that each patient receiving abortion care is provided with discharge instructions that include the following hand-outs: 1) How Much Am I Bleeding? (describing post-procedure normal and abnormal bleeding); 2) medication instructions; and 3) and surgical abortion discharge instructions, which include the facility's after-hours telephone number. DHSS's report does not state, however, that an entry is made by CHPPGP personnel in each patient's medical record that the patient received copies of those documents. That entry satisfies the regulation's requirement that written discharge instructions be provided to patients.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1120	CHPPGP objects to the deficiency identified in L1120 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that the physician providing care signed and dated the visit summary generated by the electronic health record, which reflects the medications prescribed during the patient encounter. To CHPPGP's knowledge, DHSS has not prior to its 2018 inspections interpreted this regulation to require each separate portion of a patient's medical record be signed and authenticated by the treating physician. As CHPPGP noted during the on-site inspection, however, it created a hard copy form in response to the inspection at its Kansas City facility. This form will provide an additional place for the physician to sign, date, and time medication orders for each patient and will be scanned into the medical record. This entry will be duplicative of that information on the patient's visit summary.	*In progress* UPDATE: The hard copy form has already been created and is in use. It was reviewed by DHSS inspectors at the re-inspection of CHPPGP's Kansas City facility.	Administrator	The form has already been developed and is in use. The center manager will review electronic health records for all patients receiving abortion care for one month after the form has been in use to monitor for compliance.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1122	CHPPGP objects to the deficiency identified in L1122 to the extent it misstates the nature of the information conveyed during the survey process. For each of the patient records reviewed by the surveyor, a physician or qualified health professional (as defined by § 188.027, RSMo) provided the state-mandated information to patients receiving abortion care. The records described in L1122 reflected that persons meeting the statutory and regulatory definitions gave the required information. CHPPGP's physician *elected* to note in a number of patient records that she had delivered state-mandated information; however, that notation was only intended to duplicate what the other records in each patient's record showed: that required personnel delivered the information. CHPPGP's physician simply went above and beyond by reiterating that she had followed state law. To the extent that notation creates confusion for DHSS, CHPPGP will note for its provider that the notation is not necessary.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1124	CHPPGP objects to the deficiency identified in L1122 *in part* to the extent it misstates the nature of the information conveyed during the survey process. At the time of inspection, two state-mandated reports, Induced Termination of Pregnancy (ITOP) reports, had already been submitted to DHSS as required but had not yet been scanned into the patients' electronic medical record. CHPPGP staff located both reports on the day of inspection, and they have since been scanned into the patients' electronic records. Additionally, CHPPGP has revised its indexing process. Administrative personnel continue to handle the submission of ITOP reports to DHSS, but the center manager now submits reports for each procedure by the close of business on the day the procedures were performed.	Completed 8/15/2018 UPDATE: The indexing process has already been revised, and the new process is in place.	Center manager and regional director (administrator)	Regional Director will be responsible for monitoring new process and verifying that all ITOP reports are submitted pursuant to revised procedure.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
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L1130	The director of clinical quality risk management will conduct a comprehensive training with facility staff to serve as a refresher course on CHPPGP's infection control program. CHPPGP's health center manager will also perform quarterly audits to ensure ongoing compliance after the education session.	Training will be conducted by 9/30/2018 UPDATE: A training is scheduled for 9/25/2018 at 10 a.m., and quarterly audits will be performed as outlined.	Director of clinical quality risk management and administrator	Regional director (administrator) will conduct unannounced audits after completion of training on a quarterly basis.	N/A

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced state licensure revisit was conducted on 09/26/18 to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	{L 000}		
{L1084}	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the Abortion Facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the soiled room; - Dispose of used, soiled single-use suction tubing; - Dispose of a soiled reusable series connecting hose (clear secondary suction tubing); and - Clean and disinfect a reusable glass suction bottle. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included:	{L1084}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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{L1084}	Continued From page 1 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. - Recommendation III.c. * Operating and procedure rooms must be cleaned after each patient. - Recommendation V.a.1. * Areas and items that should be cleaned on a schedule include clean and soiled storage areas and sterile storage areas. 2. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - Centers for Disease Control and Prevention (CDC); - Association for Professionals in Infection Control and Epidemiology (APIC); - Association for the Advancement of Medical Instrumentation (AAMI); and	{L1084}		

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{L1084}	Continued From page 2 - AORN. 3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed: - The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment. 4. Review of the facility's "Infection Prevention Manual" policy titled, "Directions for Cleaning and Disinfection - Abortion Procedure Suction Tubing," dated 08/15, showed: - Single-use suction tubing must be disposed of as an infectious waste after each patient use. - Multi-use suction tubing is first cleaned by running water through the tube, removing all blood and bioburden immediately after the procedure. Then soak tubing in chemical disinfectant ad per manufacturer's instructions for semi-critical devices. 5. Observation on 09/26/18 at 9:40 AM of the procedure room showed: - The metal suction machine cabinet had numerous rusted areas (uncleanable surface); - There was a used, single-use suction tubing connected to a plastic suction canister. The single-use tubing contained reddish colored fluid; - A reusable series connecting hose on the top of the machine had a blackish-gray substance on the inside the length of the tubing; and - The reusable series connecting hose was connected to a reusable glass suction bottle. There was a layer of dried black substance in the bottom of the bottle. During an interview upon the observation Staff C, Health Center Manager, stated that the replacement reusable series connecting hose	{L1084}		

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{L1084}	Continued From page 3 was on back order. 6. Observation on 09/26/18 at 9:50 AM of the storage room showed the metal cabinet of a second suction machine had numerous rusted areas, old peeling tape, dried adhesive residue on the front surface, (uncleanable surfaces) and a dried brown spill down the side of the machine that was approximately six-inches long. 7. During an interview on 09/26/18 at 9:55 AM, Staff C stated that: - The substance in the single-use suction tubing was most likely bodily fluid; - Their last procedure had been the previous Friday (09/21/18); - She did not think they had used the suction machine that day; and - The blackish gray substance in the secondary reusable series connecting hose was mold. 8. During an interview on 09/26/18 at 12:00 PM, Staff I, Maintenance, stated that the replacement for the reusable series connecting hose was located inside the suction machine cabinet. Staff C stated that she was not aware that the secondary replacement reusable series connecting hose was inside the suction cabinet. 9. During an interview on 09/26/18 at 2:10 PM, Staff C stated that: - She identified the problem (blackish gray residue) inside the reusable series connecting hose a couple of months previously (probably July) and began trying to find replacement tubing; - They continued to use the machine (with the reusable series connecting hose that had blackish gray residue inside) on patients after they identified the issue; and - She had talked with other people about the	{L1084}		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L1084}	Continued From page 4 issue with the reusable series connecting hose and it was not an infection control issue. 10. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, dated 2017, showed: - 3.3.6.4 Sterile storage: * Open or wire shelving is suitable for confined storage areas, provided that proper attention is given to traffic control, area ventilation, and housekeeping. * Storage areas should be designed to protect sterile items and their packaging from damage. - 11.1.1 Storage Facilities: * The bottom shelf of storage carts or shelving should be solid. 11. Observation on 09/26/18 at 10:00 AM of the recovery room medication supply room showed a metal storage shelving unit. There was no bottom barrier on the bottom shelf. The shelf was placed over a submersible sump pump (used to remove water that has accumulated in a water-collecting sump basin) installed in the floor. 12. Observation on 09/26/18 from 10:05 AM to 10:10 AM of exam room #1 and #2 showed each room contained a pressed wood table with chipped paint exposing the pressed wood (uncleanable surface). 13. Observation on 09/26/18 at 10:10 AM of the soiled room showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue. During an interview upon the observation, Staff C stated that housekeeping staff were responsible	{L1084}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L1084}	Continued From page 5 to clean and confirmed the cabinet was not clean.	{L1084}		
L1113	19 CSR 30-30.060(2)(K) The facility shall ensure, each patient prep The facility shall ensure that each patient is prepared for the abortion in a manner that facilitates her safety and comfort. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure equipment used for patient care was approved for use in healthcare facilities. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included: 1. Review of the FDA/Consumer Product Safety Commission (CPSC) document titled, "FDA/CPSC Public Health Advisory - Hazards Associated with the Use of Electric Heating Pads", dated 12/12/95, showed: - The FDA and CPSC have received many reports of injury and death from burns, electric shock and fires associated with the use of electric heating pads. - An electric heating pad can be dangerous for patients with decreased temperature sensation and patients taking medication for pain. - Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting. FDA and CPSC recommend the following precautions be taken to avoid hazards associated with the use of electric heating pads:	L1113		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1113	Continued From page 6 - Never [partial list]: * Use on a person who has skin that is not sensitive to temperature changes (e.g. sedated or medicated for pain). * Use in an oxygen enriched environment or near equipment that stores or emits oxygen. 2. Observation 09/26/18 at 9:30 AM in the recovery room showed: - Four recovery chairs with heating pads draped across the backs. - Three of the four heating pads were labeled "For Household Use Only" and the fourth heating pad was not labeled. - The fourth heating pad cover showed a one inch streak of clear, hard surface matter with a small circular bead of clear material at the top on the heating pad cover. 3. During an interview on 09/26/18 at 1:45 PM, Staff C, Health Center Manager, stated that: - The heating pads were for household use and needed to be removed. - She did not believe the facility had a policy for the use of heating pads.	L1113		

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4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 29, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

Enclosed please find CHPPGP's second plan of correction, which corresponds with the statement of deficiencies we received from your office yesterday afternoon.

I am pleased to note that all of the issues identified had been addressed prior to our receipt of the statement. As you know, however, there are a number of items we have purchased but not yet received, including the side tables and heating pads.

We include with this plan of correction only one exhibit: the same information we submitted to the Department yesterday prior to our receipt of the statement.

Thank you in advance for your prompt review of our plan. We look forward to resolving any outstanding issues.

Sincerely,

Vicki Casey
Regional Director for Health Center Operations
Facility Administrator

Enclosures: Second Plan of Correction
Signed Statement of Deficiencies
September 28, 2018 CHPPGP letter to DHSS and attachments

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced state licensure revisit was conducted on 09/26/18 to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	{L 000}		
{L1084}	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the Abortion Facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the soiled room; - Dispose of used, soiled single-use suction tubing; - Dispose of a soiled reusable series connecting hose (clear secondary suction tubing); and - Clean and disinfect a reusable glass suction bottle. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included:	{L1084}		

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date	8/14/2018 (first survey) 9/26/2018 (second survey)
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	Statement of Deficiencies (SOD): L-tags	L1084; L1113

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

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MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP objects to the deficiency identified in L1084 to the extent it misstates the nature of the information conveyed during the survey process. CHPPGP offers the following responses: 1. Suction machine cabinet: As outlined in CHPPGP's initial plan of correction, CHPPGP's facilities coordinator planned to perform maintenance on the cabinet by October 31, 2018. Because DHSS performed its inspection in close proximity to the expiration date of CHPPGP's license, CHPPGP agreed to DHSS's request that it shorten its timeline to ensure the task would be completed prior to Oct. 2. The maintenance was performed on September 26 as DHSS surveyors observed, and pictures have already been produced to DHSS reflecting the maintenance.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	2. Single-use suction tubing: CHPPGP disposed of the tubing on the date of the survey, and pictures have already been produced to DHSS reflecting resolution.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).
	3. Connecting hose: CHPPGP's facilities coordinator replaced the hose on the date of the survey (as state surveyors observed) and identified the discoloration as dust or dirt. He did not identify mold and, importantly, DHSS performed no tests that could have identified mold. Any conclusions drawn by surveyors were therefore speculative. CHPPGP notes that there are multiple inaccuracies contained within the statement of deficiencies regarding the connecting hose. DHSS wrongly states that CHPPGP personnel described the hose as having "mold." The staff person did not agree with surveyors that there was mold and instead stated that she did not know what the substance was. Additionally, staff had worked to locate a replacement hose and did not believe the one they had ordered and placed in the machine's cabinet fit the machine. The facilities coordinator was able to use that	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	replacement piece, however, and the maintenance is now complete. The machine was used for only two procedures between July and September 2018. At all times CHPPGP and its personnel used aseptic non-touch technique and ensured that any instruments coming into contact with the uterus were sterile.				
	4. Suction bottle: The machine's bottles have been replaced by plastic canisters, as shown in the pictures already produced to DHSS. Additionally, CHPPGP notes that the bottle was part of the suction function of the machine and was not connected to any equipment that came into contact with patients.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).
	5. Secondary suction machine: Maintenance has been performed on the machine, which was not in use, and any issues identified have been resolved. Pictures have already been produced to DHSS.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 2).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	6. Storage shelf: At DHSS's request, CHPPGP replaced the shelving unit in its supply room with a metal unit. It has since ordered a shelf guard for the lowest shelf and previously produced the receipt of purchase to DHSS. According to the vendor, delivery is anticipated on Monday, October 1.	Shelf guard ordered prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (copy of shelf guard receipt).
	7. Tables: CHPPGP had ordered replacement tables (on which staff take notes) prior to DHSS's second survey on September 26; however, it is CHPPGP's understanding that delivery has been delayed due to Hurricane Florence. CHPPGP previously produced the receipt of purchase to DHSS.	Tables ordered prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (copy of tables receipt).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	8. Soiled room sink: As discussed with surveyors on the date of their visit, the residue was caused by detergent and was removed on the date of the visit. Additionally, CHPPGP discussed in great detail with surveyors during the visit that it had conducted multiple meetings with its environmental services cleaning provider to review expectations and planned to begin performing additional daily inspections to assess the provider's work.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (copy of tables receipt).
L1113	CHPPGP has already ordered four medical-grade heating pads for its recovery room. It previously produced the receipt of purchase to DHSS. Because the pads are for patient comfort in the recovery room and are not medically necessary, CHPPGP will remove the pads from use until the new pads are received.	Completed prior to receipt of statement of deficiencies.	Health Center Manager	The facility's Health Center Manager will ensure the new heating pads are used.	*See* Exhibit A (copy of heating pads receipt).

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September 28, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

As requested by DHSS surveyors during the re-inspection of the Columbia facility operated by Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP"), CHPPGP has enclosed with this letter a number of items documenting compliance with its plan of correction. I believe you spoke with a maintenance employee while he performed work on CHPPGP's two suction machines on September 26; however, we wanted to include photographs of his finished work for your review. We have also included the final sign-in sheet for the hand-washing refresher course provided by CHPPGP's director of compliance and quality risk management.

I also wanted to provide you with an update on the timing of delivery for the new desks. It was my understanding during the first inspection that evidence of the receipt of purchase was sufficient for inspection purposes, and we produced the receipt that day. At the Department's request, shortened the internal timelines for completing many items on our plan of correction; however, we are unable to shorten the delivery time for the desks. We still anticipate that they will be delivered any day, but it's our understanding that Hurricane Florence has caused some delay. We intend to call the vendor today to check on timing and will produce pictures of the desks once delivered.

Additionally, although we have not yet received the revised statement of deficiencies, we have ordered four new medical-grade heating pads and a splash guard for the bottom shelf of the closet shelving unit, as discussed during your visit. Copies of those receipts are enclosed.

As you know, we are eager to resolve any outstanding issues to ensure that we receive our license in a timely manner and are not forced to have an interruption in services for our patients. We appreciated hearing from you on Wednesday that you plan to expedite any follow-up plan of correction in an effort to proceed as quickly as possible.

Sincerely,

Vicki Casey
Regional Director for Health Center Operations
Facility Administrator

Enclosures: Photographs of suction machines (Serial Nos. 11310 and 2M1917)
Hand-washing course sign-in sheet
Receipts for heating pads and shelf guard

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In-Service Documentation

Location: Columbia
Manager: [redacted]
Date of Training: 9/27/18
Length of Training: 20 min
Title/Topic: Infection Prevention - Hand Washing
Name of Presenter: [redacted]
Presenting Agency: PPGP

STAFF IN ATTENDANCE

Printed Name	Signature
[redacted] NP	[redacted]
[redacted]	
Note: Both nurse practitioners, a licensed practical nurse, the health center manager, and the regional director of health center operations completed the training. A separate sheet reflecting the physician's participation was previously produced to surveyors.	

Managers should complete this form for all required and optional in-service trainings, asking each staff member in attendance to print and sign their names. Attach any additional required pieces of training documentation and submit a copy to the Human Resources Department.

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CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

CHPPGP aspiration machine
Serial No. 11310

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CHPPGP aspiration machine
Serial No. 11310

CHPPGP Second Plan of Correction
Exhibit A - Page 007

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

[redacted]
[redacted]

Subject: Heating Pads
Date: Friday, September 28, 2018 1:34:15 PM

NS
Home Supply

Home Retail Products Who

Thank you. Your order has been received.

ORDER NUMBER:	DATE:	EMAIL:	TOTAL:	PAYMENT METHOD:
6618	September 28, 2018	[redacted]	$190.00	Credit Card

ORDER DETAILS

PRODUCT	
Analog Medical Grade Heating Pad - Medium (18 In. x 14 In.) × 4	
SUBTOTAL:	
SHIPPING:	
PAYMENT METHOD:	
TOTAL:	

BILLING ADDRESS

[redacted]
4401 W 109th St Suite200
Overland Park KS, KS 66211

5732686507

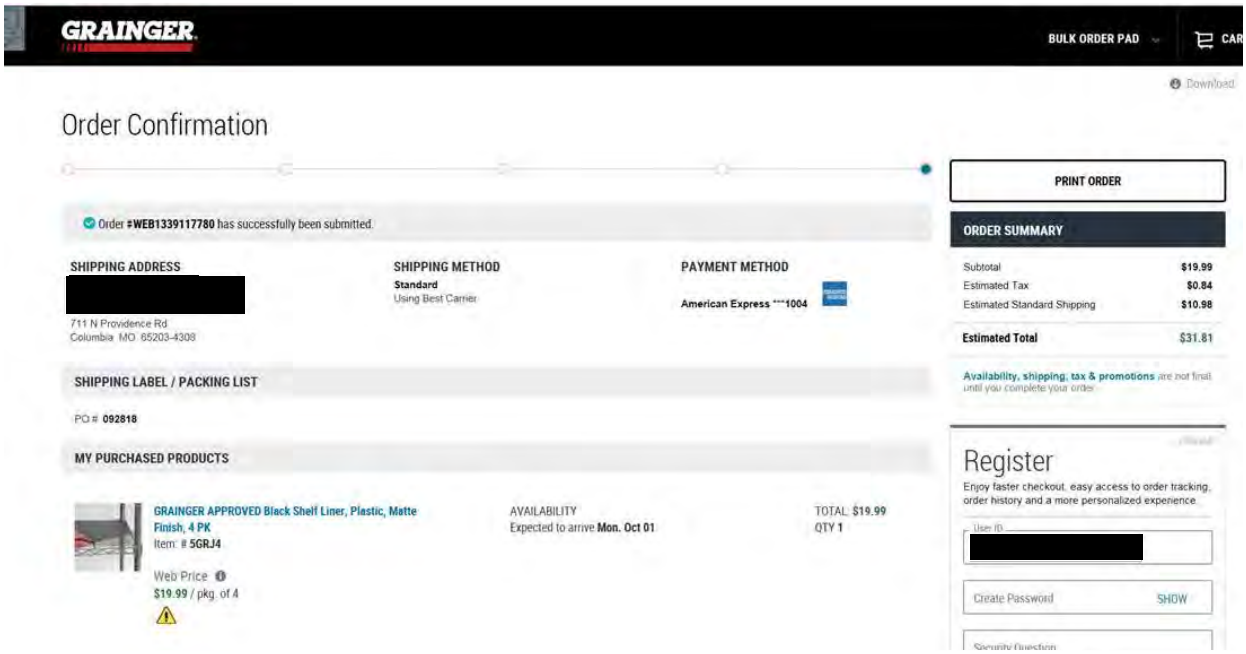
SHIPPING ADDRESS

[redacted]
711 N Providence Rd
Columbia, MO 65203

Americans United for Life

[redacted]

[redacted]
Sent: Friday, September 28, 2018 1:20 PM
[redacted]
Subject: Shelf Guard



[redacted]
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
[redacted]

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

October 16, 2018

Vicki Casey
Comprehensive Health of Planned Parenthood Great Plains, Inc.
711 N Providence Road
Columbia, MO 65203

RE: ***PoC Rejection***

Dear Vicki Casey:

On September 29, 2018 our Bureau received your Plan of Correction as a result of a Licensure revisit inspection conducted on September 26, 2018. Your Plan of Correction is **unacceptable** as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

In reference to the deficiency identified in ***L-1084-*** The Plan of Correction fails to indicate the date the correction will be fully implemented for each example. Further, the Plan of Correction fails to identify the systemic changes that will be implemented to ensure that the deficient practice will not recur. The description must be specific, realistic and complete.

Additionally, please provide information regarding any and all efforts made by your agency since August 14, 2018, to notify abortion patients of their potential exposure to an infection control risk.

Please submit a revised Plan of Correction with the above mentioned information as soon as possible via email to BAC@health.mo.gov or fax to (573) 751-6648 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570. I have attached a detailed instruction sheet for your reference.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name		Survey Exit Date	
Facility Address/ City/Zip		Statement of Deficiencies (SOD): L-tags	

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction. Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. **(TAG):**
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc).

   B. **(CORRECTIVE ACTION):**
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. **(WHEN):**
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. **(WHO):**
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. **(MONITORING AND/OR TRACKING PROCEDURES):**
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. **EVIDENCE/EXHIBIT ATTACHMENTS(s).** If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"

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p: (913) 345-1400
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October 30, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via email to Todd.Cummins@health.mo.gov, William.Koebel@health.mo.gov, and BAC@health.mo.gov

Dear Mr. Cummins,

Enclosed please find CHPPGP's revisions to its second plan of correction, which add additional information to our prior submission.

Revised Plan of Correction

While your letter dated October 16, 2018 states that CHPPHP's September 29 Plan of Correction "fails to indicate the date the correction will be fully implemented for each example," CHPPGP has repeatedly contacted DHSS – before and after receiving the revised statement of deficiencies – to ensure the Department was aware that we had already taken steps to address issues raised by DHSS, as demonstrated by multiple emails and photos sent to your office. Additionally, CHPPGP had already purchased prior to submitting the September 29 plan of correction, items at DHSS's request that were not raised in the first statement of deficiencies. CHPPGP produced receipts at the time of purchase and subsequently provided photos to your office when those items were received on October 1 (via email to former General Counsel Nikki Loethen) and October 3 (via email to you and Mr. Koebel) to confirm with DHSS that they were in place.

Specific steps regarding ongoing monitoring and inspection of the procedure room and its equipment have been included in this revised plan. New or revised sections of the amended plan are in **blue**.

Notification

Your October 16 letter also asked for information regarding notification to abortion patients of a potential exposure to an infection control risk since August 14, 2018. For the reasons laid out in CHPPGP's September 29 Plan of Correction, CHPPGP believes there has been no patient exposure to an infection control risk, and certainly none that would make a patient notification appropriate under applicable guidelines. However, CHPPGP's highest priority is to ensure patient access to care in Columbia, and as DHSS is well-aware, because CHPPGP cannot currently provide abortions in Columbia women are being forced to travel hundreds of miles to access care. For that reason, as set forth more fully below, in the interest of resolving this licensing issue CHPPGP has provided the requested patient notification to the single patient in whose procedure the suction machine was used after August 14, 2018.

CHPPGP's director of compliance and quality risk management (CQRM) has analyzed guidelines produced by the Centers for Disease Control and Prevention (CDC) to determine whether any patient notification is appropriate regarding the connecting tube on the suction machine. The CDC guidance focuses on risks of potential *bloodborne pathogen transmission*, which is not at issue here. Even

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when analyzing the risk of bloodborne pathogens, such as Hepatits B or HIV, the CDC recognizes that not all potential risks are alike, and the appropriateness of patient notification depends on the type of potential breach. The CDC outlines two categories of potential breaches: 1) Category A, which includes breaches for which the assessed risk includes "documented bloodborne pathogen transmission in association with similar practices in the past, or the observed or very high likelihood of blood exposure as a result of the breach"; and 2) Category B, breaches "where the likelihood of blood exposure . . . is uncertain, but thought to be less than would occur with a Category A breach."[1] An example of a Category A breach includes the reuse of needles or syringes between patients, which is wholly dissimilar to CHPPGP's situation. A Category B example – colonoscope reprocessing performed with incorrect disinfectant solutions – is more comparable to the tubing issue; however, it too focuses on potential bloodborne pathogen transmission from equipment that *enters the body*, which is significantly different than the facts here, where the tube makes no contact with a patient.

In the instance of a Category B breach, "the decision to notify and/or test patients should be based on a number of factors including the information gathered and assessment of the breach and should involve key stakeholders." The CDC further notes that for category B breaches, the duty to notify should be weighed against potential harm from notification.[2]

Nevertheless, in an abundance of caution and given the critical importance of swiftly bringing this license renewal process to a close to ensure CHPPGP can provide abortion services in Columbia to patients who need them, on October 24 CHPPGP notified the one patient whose procedure involved the suction machine after August 14, 2018 by both telephone and the attached letter of the tube-related incident. The patient confirmed she has had no post-procedure complications or concerns.

We look forward to hearing from you soon to complete the licensure process.

Sincerely,

Brie Anderson
Vice President of Health Services

Enclosures: Revised Second Plan of Correction and Exhibits A–D
Redacted Patient Notification Letter

Americans United for Life

[1] Centers for Disease Control & Prevention, Steps for Evaluating an Infection Control Breach, *available at* https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html.
[2] *Id.*

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October 24, 2018

[redacted]

Dear [redacted]:

I am contacting you to follow up on our conversation on October 24, 2018 regarding your care at Comprehensive Health of Planned Parenthood Great Plains (CHPPGP) in September 2018.

As discussed during that call, the Missouri Department of Health and Senior Services has requested that we notify you of a potential exposure relating to medical equipment we used during your care. The Department raised concerns after a recent inspection that a tube in the machine, which does not come into contact with the patient, was discolored. The source of the discoloration was not identified. The tubing in the machine had been cleaned, and we believe the machine and tube were safe for use. We have decided to replace the tube periodically so it will not become discolored again.

Our first priority is high quality patient care, and we apologize for any concern this issue may cause. Please contact me if you have any questions or need additional information:

[redacted] RN MSN CPHQ
Director of Compliance and Quality Risk Management
Phone: [redacted]
Email: [redacted]@PPGreatPlains.org

Again, thank you for speaking with me today. I was pleased to hear that you have not experienced any complications or concerns since your appointment with us, and I hope that you will consider CHPPGP for your future health care needs.

Sincerely,

[redacted]
Director of Compliance & Quality Risk Management

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date	8/14/2018 (first survey) 9/26/2018 (second survey) **10/16/2018 (third POC requested by DHSS)**
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	Statement of Deficiencies (SOD): L-tags	L1084; L1113

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D." above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP objects to the deficiency identified in L1084 to the extent it misstates the nature of the information conveyed during the survey process. CHPPGP offers the following responses: 1. Suction machine cabinet: As outlined in CHPPGP's initial plan of correction, CHPPGP's facilities coordinator planned to perform maintenance on the cabinet by October 31, 2018. Because DHSS performed its inspection in close proximity to the expiration date of CHPPGP's license, CHPPGP agreed to DHSS's request that it shorten its timeline to ensure the task would be completed prior to Oct. 2. The maintenance was performed on September 26 as DHSS surveyors observed, and pictures have already been produced to DHSS reflecting the maintenance.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	VP of Operations, Health Center Manager, Administrator/Regional Director of Health Services, Director of Compliance and Quality Risk Management	As to items 1-5 of L1084 CHPPGP has created a checklist list of post-procedure items to ensure that health center staff complete all necessary tasks between procedures. The list, which is attached as Exhibit B, outlines steps to be performed by an assigned staff member (the assisting nurse or her designee) and includes a visual inspection of the suction machine, removal and disposal of single-use tubing, cleaning of connecting tubing pursuant to the infection prevention manual, and changing of plastic canisters. These items will apply to CHPPGP's secondary suction machine when it is in use as well.	*See* Exhibit A (photos of Suction Machine No. 1) and Exhibit B (post-procedure checklist).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	2. Single-use suction tubing: CHPPGP disposed of the tubing on the date of the survey, and pictures have already been produced to DHSS reflecting resolution.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	The assisting nurse or her designee will dispose of the tube after each use, and the Center Manager and Regional Director will provide oversight as described in Column E.	CHPPGP will complete and maintain checklists for the six months following the renewal of its license to allow for oversight and review. In addition to the Center Manager completing a review of the day's checklist at the end of each day on which CHPPGP offers abortion care, the Manager will submit the checklists for approval to the Regional Director for the six-month period after CHPPGP obtains its renewed license and begins offering abortion services. The Regional Director will review and confirm the checklist has been completed and will perform periodic, unannounced visual inspections of both the primary and secondary suction machines. The Director of Compliance and Quality Risk Management will also conduct a training prior to November 9, 2018 with CHPPGP employees in Columbia to review	*See* Exhibits A and B.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	3. Connecting hose: CHPPGP's facilities coordinator replaced the hose on the date of the survey (as state surveyors observed) and identified the discoloration as dust or dirt. He did not identify mold and, importantly, DHSS performed no tests that could have identified mold. Any conclusions drawn by surveyors were therefore speculative. CHPPGP notes that there are multiple inaccuracies contained within the statement of deficiencies regarding the connecting hose. DHSS wrongly states that CHPPGP personnel described the hose as having "mold." The staff person did not agree with surveyors that there was mold and instead stated that she did not know what the substance was. Additionally, staff had worked to locate a replacement hose and did not believe the one they had ordered and	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	The assisting nurse or her designee will clean the tube at the end of each procedure day, and the Center Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.	the cleaning procedures for both suction machines. She will also conduct an annual survey inspection, which includes a visual inspection of the machines. As before, the VP of Operations will continue to oversee regular repairs and/or maintenance, including the ordering of replacement parts for the suction machines.	*See* Exhibits A and B.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	placed in the machine's cabinet fit the machine. The facilities coordinator was able to use that replacement piece, however, and the maintenance is now complete. The machine was used for only two procedures between July and September 2018. At all times CHPPGP and its personnel used aseptic non-touch technique and ensured that any instruments coming into contact with the uterus were sterile. 4. Suction bottle: The machine's bottles have been replaced by plastic canisters, as shown in the pictures already produced to DHSS. Additionally, CHPPGP notes that the bottle was part of the suction function of the machine and was not connected to any equipment that came into contact with patients.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	The assisting nurse or her designee will change the bottles after each use, and the Center Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.		*See* Exhibits A and B.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	5. Secondary suction machine: Maintenance has been performed on the machine, which was not in use, and any issues identified have been resolved. Pictures have already been produced to DHSS.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	Assigned staff will perform required tasks between procedures and the Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.		*See* Exhibits A and B.
	6. Storage shelf: At DHSS's request, CHPPGP replaced the shelving unit in its supply room with a metal unit. It has since ordered a shelf guard for the lowest shelf and previously produced the receipt of purchase to DHSS. According to the vendor, delivery is anticipated on Monday, October 1.	Shelf guard ordered prior to receipt of statement of deficiencies. Installed (and DHSS notified) on 10/1/2018.	Assigned staff will perform required tasks between procedures. Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by facilities coordinator.	The Health Center Manager will include inspection of the shelf guard (and cleaning of the guard, as necessary) as part of her daily monitoring of the performance of the environmental cleaning service provider.	*See* Exhibit A (copy of shelf receipt) and Exhibit D (October 3, 2018 email to DHSS).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	7. Tables: CHPPGP had ordered replacement tables (on which staff take notes) prior to DHSS's second survey on September 26; however, it is CHPPGP's understanding that delivery has been delayed due to Hurricane Florence. CHPPGP previously produced the receipt of purchase to DHSS.	Tables ordered prior to receipt of statement of deficiencies. New tables installed (and DHSS notified) on 10/3/2018.	Assigned staff will perform all required tasks between procedures and the Center Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.	The Health Center Manager will include inspection of the new tables as part of her daily monitoring of the performance of the environmental cleaning service provider.	*See* Exhibit A (copy of tables receipt) and Exhibit C (October 1, 2018 email to DHSS).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	8. Soiled room sink: As discussed with surveyors on the date of their visit, the residue was caused by detergent and was removed on the date of the visit. Additionally, CHPPGP discussed in great detail with surveyors that it had conducted multiple meetings with its environmental services cleaning provider to review expectations and planned to begin performing additional daily inspections to assess the provider's work.	Completed prior to receipt of statement of deficiencies. Sink cleaned 9/26/2018. Second meeting with environmental cleaning on 9/26/2018.	VP of Operations and Health Center Manager	The Health Center Manager will include inspection of the sink as part of her daily monitoring of the performance of the environmental cleaning service provider. The VP of Operations will continue to provide oversight of cleaning service provider performance.	
L1113	CHPPGP has already ordered four medical-grade heating pads for its recovery room. It previously produced the receipt of purchase to DHSS. Because the pads are for patient comfort in the recovery room and are not medically necessary, CHPPGP will remove the pads from use until the new pads are received.	Completed prior to receipt of statement of deficiencies. Medical-grade pads received (and photos sent to DHSS) on 10/3/2018.	Health Center Manager	The facility's Health Center Manager will ensure the new heating pads are used.	*See* Exhibit A (copy of heating pads receipt) and Exhibit D (October 3, 2018 email to DHSS).

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September 28, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

As requested by DHSS surveyors during the re-inspection of the Columbia facility operated by Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP"), CHPPGP has enclosed with this letter a number of items documenting compliance with its plan of correction. I believe you spoke with a maintenance employee while he performed work on CHPPGP's two suction machines on September 26; however, we wanted to include photographs of his finished work for your review. We have also included the final sign-in sheet for the hand-washing refresher course provided by CHPPGP's director of compliance and quality risk management.

I also wanted to provide you with an update on the timing of delivery for the new desks. It was my understanding during the first inspection that evidence of the receipt of purchase was sufficient for inspection purposes, and we produced the receipt that day. At the Department's request, shortened the internal timelines for completing many items on our plan of correction; however, we are unable to shorten the delivery time for the desks. We still anticipate that they will be delivered any day, but it's our understanding that Hurricane Florence has caused some delay. We intend to call the vendor today to check on timing and will produce pictures of the desks once delivered.

Additionally, although we have not yet received the revised statement of deficiencies, we have ordered four new medical-grade heating pads and a splash guard for the bottom shelf of the closet shelving unit, as discussed during your visit. Copies of those receipts are enclosed.

As you know, we are eager to resolve any outstanding issues to ensure that we receive our license in a timely manner and are not forced to have an interruption in services for our patients. We appreciated hearing from you on Wednesday that you plan to expedite any follow-up plan of correction in an effort to proceed as quickly as possible.

Sincerely,

Vicki Casey
Regional Director for Health Center Operations
Facility Administrator

Enclosures: Photographs of suction machines (Serial Nos. 11310 and 2M1917)
Hand-washing course sign-in sheet
Receipts for heating pads and shelf guard

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In-Service Documentation

Location: Columbia
Manager: [redacted]
Date of Training: 9/27/18
Length of Training: 20 min
Title/Topic: Infection Prevention - Hand Washing
Name of Presenter: [redacted]
Presenting Agency: PPGP

STAFF IN ATTENDANCE

Printed Name	Signature
[redacted] NP	[redacted]
[redacted]	
Note: Both nurse practitioners, a licensed practical nurse, the health center manager, and the regional director of health center operations completed the training. A separate sheet reflecting the physician's participation was previously produced to surveyors.	

Managers should complete this form for all required and optional in-service trainings, asking each staff member in attendance to print and sign their names. Attach any additional required pieces of training documentation and submit a copy to the Human Resources Department.

Americans United for Life

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

CHPPGP Second Plan of Correction
Exhibit A - Page 007

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

[redacted]
[redacted]

Subject: Heating Pads
Date: Friday, September 28, 2018 1:34:15 PM

NS
Home Supply

Home Retail Products Who

Thank you. Your order has been received.

ORDER NUMBER:	DATE:	EMAIL:	TOTAL:	PAYMENT METHOD:
6618	September 28, 2018	[redacted]	$190.00	Credit Card

ORDER DETAILS

PRODUCT	
Analog Medical Grade Heating Pad - Medium (18 In. x 14 In.) × 4	
SUBTOTAL:	
SHIPPING:	
PAYMENT METHOD:	
TOTAL:	

BILLING ADDRESS

[redacted]
4401 W 109th St Suite200
Overland Park KS, KS 66211

5732686507

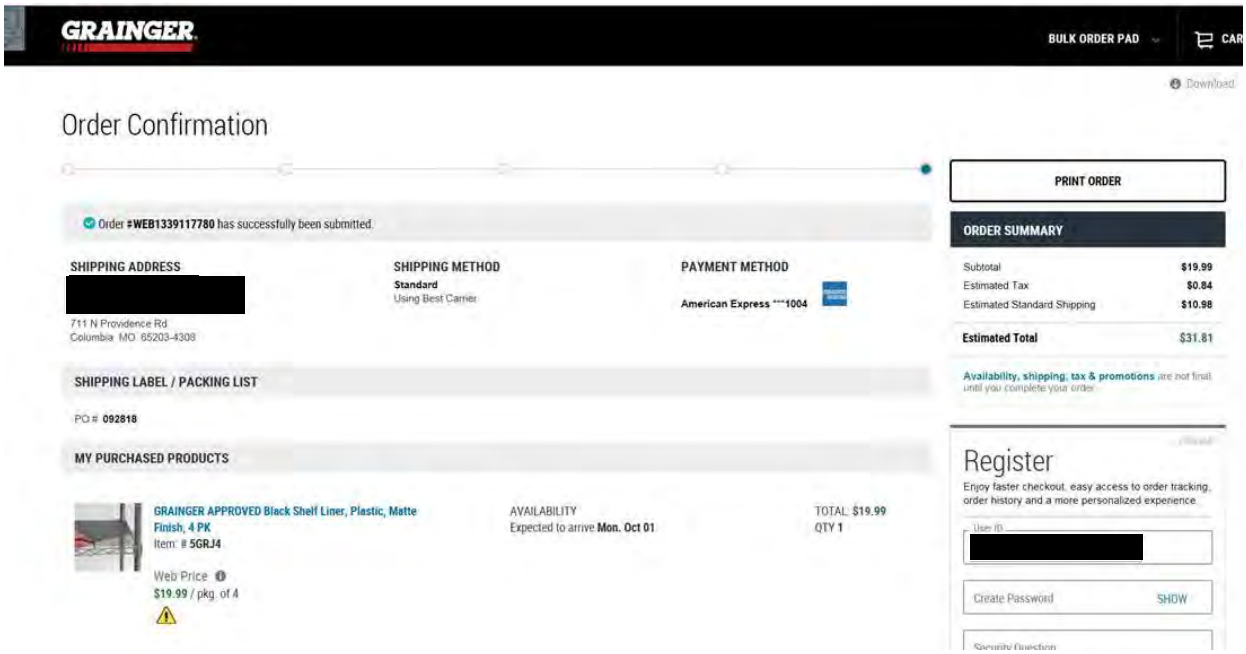
SHIPPING ADDRESS

[redacted]
711 N Providence Rd
Columbia, MO 65203

Americans United for Life

[redacted]

[redacted]
Sent: Friday, September 28, 2018 1:20 PM
[redacted]
Subject: Shelf Guard



[redacted]
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
[redacted]

Americans United for Life

For Plan of Correction Monitoring – CHPPGP Columbia Facility

DATE OF SERVICE: _____

COMPLETED AFTER PATIENT: 1___ 2___ 3___ 4___ 5___ 6___ 7___ 8___ 9___ 10___

COMPLETED BY: _____

Post-Procedure Room Cleaning Checklist

This list is to be used as a guide/quick reference and is not a substitute for the information found in the Infection Prevention Manual. Please see the Infection Prevention Manual for detailed information about specific disinfecting and sterilizing procedures. Follow all directions on each individual cleaning product used.

After Every Procedure:

- ☐ Remove used instruments and place in the dirty room to be cleaned, disinfected and sterilized as required.
- ☐ Replace paper on exam table after wiping exam table with disinfectant wipes and allowing to dry.
- ☐ Replace covers on leg/foot holders.
- ☐ Wipe down all procedure lights including the swing arm light handle and the gooseneck light. Disinfect any spray bottles/other equipment that is not disposable and was not placed inside a sterile cover.
- ☐ Throw out any medications including multi-use vials that were brought into the procedure room (whether or not the patient used them).
- ☐ Collect and remove waste.
- ☐ Collect and remove soiled linen, if any.
- ☐ Clean and disinfect blood pressure cuffs, monitor leads, etc.
- ☐ Wipe down the exam table and other horizontal surfaces that came into contact with patient (including wheelchair, if used) with germicidal disposable wipes.
- ☐ Clean floor with disinfectant wipe around exam table if there are bodily fluids present.
- ☐ Wipe down Procedure trays/carts with germicidal disposable wipes.

If the ultrasound machine was used:

- ☐ Wipe the abdominal transducer with Sono-Wipes.
- ☐ If trans-vaginal probe was used, probe must be sterilized for 8 minutes using Revital–Ox Resert High Level Disinfectant located in the scrub area in the change room then rinse well under running water.
    - Controls must be done prior to disinfecting.
    - Log book for Revital-Ox is located in the procedure room cabinet.

If suction machine was used:

- ☐ Wipe with germicidal disposable wipes and do visual inspection of machine.
- ☐ Remove canister and wipe inside the canister holders.
- ☐ Canisters must be changed, cleaned, disinfected and dried between patients.
- ☐ Single use tubing must be disposed of as infectious waste after each patient.

Americans United for Life

From: Wales, Emily
To: "Loethen, Nikki"
Subject: Checking in re: Columbia license
Date: Monday, October 01, 2018 4:02:00 PM

Hi, Nikki.

I left a message with Emily in your office, but I thought I'd send you a quick email, as well. As you know, the abortion facility license for our Columbia health center is set to expire tomorrow. I'm sure you're aware that we received a new statement of deficiencies on Friday, and we submitted a second plan of correction Saturday.

Fortunately, all of the issues had already been addressed prior to our receipt of the statement. I would note, just so it's clear, that even the requests that we replace or purchase new equipment have been resolved. The items we're replacing that haven't yet arrived from vendors – tables and heating pads – aren't necessary for patient care, so we've removed them, and the shelf guard for our supply room has been purchased and installed.

I wanted to ensure that DHSS's surveyors knew they were welcome to return for a follow-up inspection at any time. We are, of course, eager to keep this process moving to ensure patients are able to access services, and we have patients scheduled this Wednesday and next Tuesday. I know that this inspection process has come down to the wire before, so I'm hopeful we can work together to resolve things in a timely manner.

As always, don't hesitate to call if you have any questions or would like to discuss our license.

Emily

Emily Wales
General Counsel and Chief Compliance Officer
Planned Parenthood Great Plains (PPGP)
Planned Parenthood Great Plains Votes (PPGPV)
P: 913-345-4613
www.PPGreatPlains.org | www.PPGPVotes.org

**Licensed in Missouri and Kansas*

[redacted]

[redacted]

[redacted]

From: Casey, Vicki
Sent: Wednesday, October 03, 2018 4:59 PM
To: 'Cummins, Todd'; 'william.koebel@health.mo.gov'
Subject: RE: CHPPGP Plan of Correction

Bill and Todd,

I wanted to pass along one more update regarding our plan of correction. The new heating pads and tables have been received at the health center, as you'll see in the attached photographs. (We've left the pads in the boxes in case you have questions.) You'll note, of course, that there are still four chairs in the recovery room, as we have not yet heard a response on the waiver.

Please let me know when we can expect an update on the approval status of our plan of correction and the waiver request.

Have a good evening.

Vicki Casey
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
PH: 913-345-4671
vicki.casey@ppgreatplains.org

Americans United for Life

From: Casey, Vicki
Sent: Tuesday, October 02, 2018 3:00 PM
To: 'Cummins, Todd'; 'william.koebel@health.mo.gov'
Subject: CHPPGP Plan of Correction

Bill and Todd,

I just tried to call both of you but wasn't able to reach you. I wanted to check with you on the status of our Columbia license, as the license expires today. I believe you both know we have patients on the schedule tomorrow, and as I stated in my letter to you Friday, all of the issues you raised last week have been addressed.

Also, I wanted to make sure you had the latest information about the new equipment we've ordered. The shelf guard has been installed, and the new tables and heating pads have been ordered. Both should be arriving soon, but since those items aren't necessary for patient care, we've removed the old tables and pads from patient areas. And, of course, you have the photographs of the repaired machines, as you requested during your visit.

Please don't hesitate to give me a call if you'd like to discuss anything. I look forward to hearing from you soon.

Vicki

Vicki Casey
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
PH: 913-345-4671
vicki.casey@ppgreatplains.org

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 12/06/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments A second onsite revisit was conducted at the facility on December 06, 2018 to evaluate the correction of deficiencies cited on the August 14, 2018 licensure survey. An in-person interview was conducted offsite with the facility's physician to evaluate compliance with applicable requirements. All deficiencies cited during the August 14, 2018 licensure survey were found to be corrected. The facility was found to be in compliance with all legal requirements.	{L 000}		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

December 14, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains, Inc.
711 N Providence Road
Columbia, MO 65203

RE: ***Second Revisit Licensure Survey***

Dear Vicki Casey:

Please see attached results of the recent follow-up survey on ***December 6, 2018***. This relates to the Licensure Survey conducted ***August 14, 2018***. Your facility is now compliant with all deficiencies previously cited.

Abortions shall not be performed at CHPPGP until the facility is licensed and in compliance with all applicable laws, including but not limited to the hospital privileges requirements. *See* §§ 188.027, 188.080 & 197.215 RSMo; 19 CSR 30-30.060(1)(C)(4).

Please retain this material for your own records.

Please contact the Bureau of Ambulatory Care with any questions at 573-751-1588 or BAC@health.mo.gov.

Respectfully,

Melinda Laughlin RN, BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosure

Release and Settlement Agreement

This Release and Settlement Agreement is made and executed by and between Planned Parenthood of Kansas and Mid-Missouri, Inc., (hereinafter referred to as "PPKM"), the Missouri Department of Health and Senior Services, (hereinafter referred to as "DHSS"), Margaret Donnelly, in her official capacity as the Director of DHSS (hereinafter referred to as "Donnelly"), Chris Koster, in his official capacity as Attorney General of the State of Missouri (hereinafter referred to as "Koster"), James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, Missouri (hereinafter referred to as "Kanatzar"), and Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, Missouri (hereinafter referred to as "Knight"), (DHSS, Donnelly, Koster, Kanatzar, and Knight will hereinafter be referred to collectively as "Defendants"; PPKM and Defendants will hereinafter be referred to collectively as the "Parties.") The Parties enter into this agreement through their respective lawyers.

For due and good consideration recited herein, the Parties agree and state as follows:

1. **Plaintiff.** PPKM is the Plaintiff in lawsuits styled (1) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Jane Drummond, et al.*, No. 07-4164-CV-C-ODS, in the United States District Court for the Western District of Missouri, Central Division; (2) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00463, filed in the Cole County Circuit Court; and (3) *Planned Parenthood of Kansas and Mid-Missouri, Inc., v. Missouri Department of Health and Senior Services*, No. 08AC-CC00276, filed in the Cole County Circuit Court.

(These lawsuits will hereinafter be referred to collectively as the "Lawsuits.")

2. **Defendants.** Defendants are named as the defendants in the Lawsuits.

3. **Scope of Agreement.** This Agreement embodies the entire agreement and understanding of the Parties with respect to the subject matter contained herein. The Parties hereby declare and represent that no promise, inducement, or agreement not herein expressed has been made, and the Parties acknowledge that the terms and conditions of this Agreement are contractual and not a mere recital.

4. **Non-Admission.** No actions taken by the Parties, or any of them, either previously or in connection with this Agreement shall be deemed or construed to be an admission of the truth or falsity of any matter pertaining to any claim or defense alleged in the pleadings filed on behalf of the Parties in the Lawsuits, or an acknowledgment by any of the Parties of any liability to the other parties or to any person for any other claim, demand, or action, all liability being expressly denied by the Parties.

5. **Consideration.** In consideration for (1) PPKM's dismissal of the Lawsuits; (2) PPKM's release of claims as set forth in paragraph 10 of this Agreement; (3) PPKM's agreement to complete structural changes at the Columbia Center and to otherwise comply with 19 CSR 30-30.070(2), as set out in paragraph 6 of this Agreement; and (4) PPKM's agreement that the Brous Center will comply with certain provisions of 19 CSR 30-30.050 and 19 CSR 30-30.060, as set out in paragraph 7 of this Agreement, the Defendants agree that DHSS will approve the Columbia Center and the Brous Center for licensure as abortion facilities.

6. **Modifications of the Columbia Center.** PPKM agrees to make modifications to its facility located in Columbia, Missouri ("Columbia Center") as set out in the attached Addendum A. PPKM anticipates being able to begin construction within nine months of the date that this Agreement is finally signed by all the parties and completing construction within sixteen months from the date this Agreement is finally signed by all the parties, and agrees that while certain factors relevant to this timing (such as the DHSS's approval of its architectural drawings and sprinkler plans) are not under PPKM's control, it will make a good-faith effort to comply with these time frames.

PPKM agrees that it will submit architectural drawings showing the modifications to be made, as set out in Addendum A, to DHSS before work begins at the Columbia Center, including the agreed upon modifications in the sterilization and soiled rooms, and the sprinkler plans. PPKM agrees that DHSS shall be granted entry onto the Columbia Center premises for a mid-construction progress inspection. DHSS agrees that it will give PPKM at least 7 days prior notice of the proposed date for its progress inspection, which shall commence at an agreed upon date and time convenient to both parties. DHSS will be available for follow up questions and approval of specific construction or design questions as they arise and will endeavor to provide prompt responses to the Columbia Center during the construction and pre-approval phases.

PPKM agrees to permit DHSS to conduct a final inspection of the Columbia Center within 2 weeks of the completion of the structural modifications set out in Addendum A and before an abortion facility license is issued to ensure that the modifications at the Columbia

Center have been completed as agreed and also to ensure that the Columbia Center is also in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A. If this inspection reveals that the modification set out in Addendum A have not been completed as agreed, or that the Columbia Center is not in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, PPKM agrees that it will make a good-faith effort to complete the remaining work needed for the Columbia Center to complete the modifications set out in Addendum A, and to be in compliance with the other requirements of 19 CSR 30-30.070(2) that have not been modified as set out in Addendum A, within six weeks.

DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the requirements of 19 CSR 30-30.070(2) except as specifically set forth in Addendum A, and will not require changes not set forth in Addendum A unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to no longer be in compliance with those requirements.

7. **Brous Center.** PPKM will comply with the procedural, operational, and management requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, at its Brous Center location. Modifications to certain requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060 that will apply to the Brous Center are set forth in Addendum B.

PPKM agrees to permit an inspection of the Brous Center before an abortion facility license is issued to ensure that the Brous Center is in compliance with the requirements of 19 CSR 30-30.050 and 19 CSR 30-30.060, as modified by Addendum B.

The Parties acknowledge that the Brous Center currently does not perform surgical abortions. If the Brous Center at a future time wishes to provide surgical abortion services, PPKM will notify Defendants' counsel. PPKM understands that the performance of surgical abortions at the Brous Center would constitute a material change that would require the Brous Center to comply with additional regulations.

8. **Provision of Services.** It is the intention of the Parties and Defendants that the Columbia Center may continue providing abortion services throughout the process of preparing for and completing the modifications described in paragraph 6, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process. It is the intention of the Parties and Defendants that the Brous Center may continue providing medication abortion services during the abortion facility license application process, and that it shall be deemed in compliance with the requirements of the ASCLL throughout that process.

9. **Dismissal of the Lawsuits.** Upon payment of the fees and expenses set forth in Paragraph 12 of this Agreement, the Parties shall also execute the following Stipulations of Prejudicial Dismissal: (a) a Stipulation of Prejudicial Dismissal pursuant to Fed. R. Civ. P. 41(a)(1)(ii), to be filed the federal lawsuit identified in paragraph 1 of this Agreement, dismissing with prejudice PPKM's claims in their entirety; and (b) Stipulations of Prejudicial Dismissal pursuant to Mo. R. Civ. P. 67.02, to be filed in the state lawsuits identified in paragraph 1 of this Agreement dismissing with prejudice all claims raised in those lawsuits.

10. **Release.** PPKM does hereby release, acquit, and forever discharge the

Defendants, the State of Missouri, and any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, of all and from any and all liability, claims, actions, causes of action, demands, rights, damages, costs, interest, loss of service, expenses, and compensation whatsoever, whether or not now known or contemplated, which PPKM now has, or which may hereafter accrue, against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on or arising out of the allegations in the Lawsuits relating to the licensure of the Columbia and Brous Centers. PPKM specifically acknowledges that it is forever barred from filing suit against the Defendants, the State of Missouri, or any current or former employee, agent, agency, actor, or contractor of the Department or the State of Missouri, based on any claim based on or arising out of the allegations in the Lawsuits relating to licensure of the Columbia and Brous Centers.

11. **Full Consideration.** PPKM acknowledges that the consideration described in paragraph 5 of this Agreement is all that it or its representatives are ever to receive from the State of Missouri, the Defendants, or any person or entity related to them whatsoever, for the settlement described in this Agreement, whether in settlement of PPKM's claims for damages, attorney's fees, costs, or other claims which were or could have been asserted in the Lawsuits.

12. **Attorney's Fees, Costs and Expenses.** In exchange for payment of $80,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and the regulations implementing that law to the

Columbia Center, and payment of $65,000.00, representing compensation for attorney's fees and expenses generated in litigating the application of the ASCLL and regulations implementing that law to the Brous Center in the federal lawsuit, PPKM hereby waives any remaining claim it might have against the State of Missouri, the Defendants in the Lawsuits, or any current or former employee, agent, agency, actor, or contractor of the State for attorney's fees, expenses, or costs, pursuant to 42 U.S.C. § 1988, or any other statute, rule, or other provision of law which is or may be in any way applicable hereto. The payment of $145,000.00 will be issued to Plaintiff's counsel by June 30, 2010.

13. **Court Costs.** The Parties will bear their own court costs.

14. **Non-Assignment.** PPKM hereby represents, acknowledges, and warrants that it has not at any time heretofore assigned to any other person or entity all or any portion of any claim or potential claim whatsoever that it may have, or may have had, against the Defendants, the State of Missouri, or any person or entity whatsoever based on or arising out of the allegations contained in the Lawsuits.

15. **Binding Effect.** The persons signing this Agreement represent that they have read this Agreement and fully understand its provisions. The signatories of the Parties declare that they are of legal age and that they have relied solely upon their own judgment without influence of anyone in making this Agreement. This Agreement shall be binding upon, and inure to the benefit of the heirs, personal representatives, successors, and assigns of the Parties.

16. **Preparation of Documents.** This Agreement is the joint work product of the

Parties and, in the event of any ambiguity herein, no inference shall be drawn against a party by reason of document preparation.

17. **Further Execution.** Each party hereto shall execute any and all documents as are necessary or desirable to consummate the transactions contemplated hereby.

18. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Missouri.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be deemed executed as of the date the Agreement was finally signed by the Parties below.

PLANNED PARENTHOOD OF KANSAS
AND MID-MISSOURI, INC.

By: _____

Title: Attorney for PPKM

STATE OF New York)
) ss
COUNTY OF New York)

Before me, a notary public for the State of New York, personally appeared Jonn for Sandmann, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Planned Parenthood of Kansas and Mid-Missouri, Inc., and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18 day of May, 2010.

_____
Notary Public

My commission expires on 11/9/13.

DARA KLASSEL
NOTARY PUBLIC-STATE OF NEW YORK
No. 02KL4913955
Qualified In New York County
My Commission Expires 11/9/13

MISSOURI DEPARTMENT OF HEALTH
AND SENIOR SERVICES

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF Missouri)
) ss
COUNTY OF Cole)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for the Missouri Department of Health and Senior Services with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08500003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

MARGARET DONNELLY, in her official capacity as Director, Missouri Department of Health and Senior Services

By: Emily A Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Margaret Donnelly with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Margaret Donnelly, in her official capacity as Director of the Missouri Department of Health and Senior Services, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number: 08500003

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012

CHRIS KOSTER, in his official capacity as Attorney General of Missouri

By: Emily A. Dodge

Title: Assistant Attorney General

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Emily A. Dodge, who did upon her oath state that she is an attorney for Chris Koster with respect to the matter set forth in this Agreement, that she is authorized to execute this Agreement on behalf of Chris Koster, in his official capacity as Attorney General of Missouri, and that she executed this Agreement as her free act and deed. Subscribed and sworn to before me this 14th day of May, 2010.

JACKIE BLACKWELL
Notary Public - Notary Seal
State of Missouri
Commissioned for Cole County
My Commission Expires: July 08, 2012
Commission Number 08451008

Jackie Blackwell
Notary Public

My commission expires on 07-08-2012.

JAMES KANATZAR, in his official capacity as Prosecuting Attorney of Jackson County

By: _____

Title: Prosecuting Attorney

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared James F. Kanatzar, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of James Kanatzar, in his official capacity as Prosecuting Attorney of Jackson County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 26 day of May, 2010.

_____
Notary Public

My commission expires on _____.

NOTARY PUBLIC NOTARY SEAL STATE OF MISSOURI

MICHAEL A. WELLS
My Commission Expires
September 24, 2012
Jackson County
Commission #08499225

DANIEL KNIGHT, in his official capacity as Prosecuting Attorney of Boone County

By: Charles J. Dykhouse

Title: County Counselor for Boone County

STATE OF MISSOURI)
) ss
COUNTY OF)

Before me, a notary public for the State of Missouri, personally appeared Charles J. Dykhouse, who did upon his/her oath state that he/she is authorized to execute this Agreement on behalf of Daniel Knight, in his official capacity as Prosecuting Attorney of Boone County, and that he/she executed this Agreement as his/her free act and deed. Subscribed and sworn to before me this 18th day of May, 2010.

DEBORAH A. SPRAGUE
Notary Public - Notary Seal
State of Missouri
County of Boone
My Commission Expires August 10, 2012
Commission #08379045

Deborah A. Sprague
Notary Public

My commission expires on August 10, 2012.

ADDENDUM A

Work to Be Completed by Planned Parenthood of Kansas and Mid-Missouri at its Columbia Center as Described in Paragraph 6 of the Settlement Agreement

Corridors and Patient-Traveled Doors

In light of the Columbia Center's specific configuration, the Department determines that the facility's existing corridor width of 5 feet and door widths and construction are acceptable if combined with the following modifications. The door swing in the procedure and recovery rooms will be made so that they continue to swing into the room, but swing next to the wall and out of the way of the gurney. The fire extinguisher on the wall opposite the recovery room will be moved to the same side as the recovery room. The fire extinguisher adjacent to the procedure room will be moved to the same side as the procedure room. These modifications will provide extra maneuvering room for a stretcher into either room.

Construction Type/Sprinkler System

The Regulations require single story facilities to be Type II (111) construction. The facility will become fully equipped with a sprinkler system, which will be an acceptable alternative to the construction type. The design specifications for the sprinkler system must be submitted to the Department for approval before construction begins.

Dimensions for procedure room

The Regulations require the procedure room to be 12 feet length and width and a minimum ceiling height of 9 feet. The procedure room to be used by the Columbia Center is

12 feet by 9 feet, 1/2 inch, with a ceiling height of 8 feet, 6 inches. These dimensions are an acceptable alternative because the facility will only use one procedure room.

Personnel Change Rooms

The Regulations require personnel change rooms for each sex, be located convenient to the procedure room, and each equipped with a toilet and lavatory. The facility may have only one, unisex personnel change room because the facility will only use one procedure room.

Procedure Room Lighting

The Regulations require that the procedure room be equipped with a ceiling-mounted surgical light. The Department grants a deviation from this Regulation to the Columbia Facility provided that the procedure room be equipped with a wall-mounted surgical light and gooseneck light.

Patient Change Rooms

The Regulations require at least two patient change rooms with storage for personal effects. The facility shall be allowed to use only one patient change room and to have patient belongings travel with the patient in a secure container, if it uses only one procedure room and does not use the procedure room as the change room.

Counseling Room Dimensions

The Regulations require that counseling rooms shall be separate and not smaller than ten feet by ten feet (10' x 10'). The facility shall be allowed to use its counseling room that is eight feet by ten feet, eleven inches (8' x 10', 11'').

Scrub Facility

The Regulations require knee or foot-operated scrub facilities located immediately outside the procedure room. The Facility shall be allowed to use a hands-free scrub sink located in the former procedure room which will no longer be used as a procedure room, and which is adjacent to the usable procedure room.

Sterilizing Room

The Facility shall provide a sterilization room with positive air pressure in relation to adjacent areas, in accord with 19 CSR 30-30.070(2)(v). The Facility shall also provide a separate soiled/decontamination room with a constant running exhaust.

Additional Items:

The following items shall also be completed:

The facility shall install five (5) additional exit signs to clearly indicate the direction of exit travel.

The facility shall make ceiling tile in the clinical area so that it is smooth and easily cleanable.

The patient toilet facility shall be equipped with a constant running exhaust.

All open cabinet storage of supplies in the procedure room must be converted into closed cabinets in accord with the Regulations.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.070(2) shall apply in full to the Columbia Center. DHHS acknowledges that it has made two site visits to the Columbia Center, believes it to be in compliance with the

requirements of 19 CSR 30-30.070(2) except as specifically set forth above, and agrees that it will not require changes not set forth in above unless it determines that material alterations at the Columbia Center since the time of the site visits cause it to be no longer in compliance with those requirements.

ADDENDUM B

Modifications of Brous Center requirements.

The Brous Center's quality assurance program will review all medication abortion complications, but will not be required to review the following items set forth in 19 CSR 30-30.060(3)(J) that are not applicable to medication abortion: cases that resulted in a stay of more than twelve (12) hours, and cases in which gestational age was determined to be beyond eighteen (18) weeks. The quality assurance program will not be required to review intraoperative and postoperative complications, however, complications of medication abortion, including incomplete or failed medication abortions that requires surgical completion, and hemorrhaging that requires surgical intervention following a medication abortion, shall be reviewed as part of the quality assurance program.

The Brous Center will not be required to provide medication abortion in a procedure room or a recovery room, and requirements that relate to the procedure and/or recovery room are therefore inapplicable. Continuous physician services or registered professional nursing services will be provided whenever an abortion patient is in the Brous Center, once the patient has received the mifepristone or other medication that begins the abortion process. PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060 (3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)(4). 19 CSR 30-30.060(3)(H)(2) and 19 CSR 30-

30.060(4) (A) through (C) do not apply to the inducement of medication abortions at the Brous Center.

The Brous Center will provide Anti-Rh immune globulin therapy to Rh negative patients during the appointment where the patient receives the mifepristone or other medication that begins the abortion process. The Brous Center need not perform urinalysis or a pelvic exam for every abortion patient, because it performs ultrasound on every patient to confirm pregnancy and gestational age. It will also perform hematocrit or hemoglobin and RH typing on every abortion patient. The option to perform a hemoglobin test instead of a hematocrit shall apply to the Columbia Center as well as the Brous Center.

If not specifically mentioned in this Addendum, the additional regulations of 19 CSR 30-30.050 and 19 CSR 30-30.060 shall apply in full to the Brous Center.

Missouri Department of Health and Senior Services

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	A004	A. BUILDING _____ B. WING _____	06/03/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COLUMBIA CENTER, PLANNED PARENTHOOI	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments No deficiencies per Dean Linneman.	L 000		

Missouri Department of Health and Senior Services

TITLE (X6) DATE

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments An unannounced on-site state licensure survey was conducted at this facility on 06/10/13 through 06/11/13. See below for findings. UPDATE 02/25/2014. This facility was found to be NOT performing abortion procedures. As they were not performing the procedure that required a license (and had no immediate plans to do so), a new license was not provided. Discussions were started between PP and DHSS regarding this process, with PP wishing to retain some semblance of the license, if for no other reason, so that if and when they ever reopened the facilty to perform abortions, the 2010 settlement agreement on the physical standards would still be in place. In general, DHSS was OK with this, and discussion about an additional amendment to the settlement agreement continued (we "close" the license with the agreement that a future provider [at the same location] would still have the relaxed construction standards in place from 2010. However, as of Feb 2014, there seems to have been no further movement toward an additional settlement agreement. A license has NOT been generated, nor will it be for the foreseeable future. An SOD for the June 2013 survey was never issued. This SOD and related survey processes have been held up since that time. After discussion with Section Administrator Dean Linneman, it was decided to officially close the file on both the facility and the 2013 survey of PP. (Pending a later reversal by OGC). --BAC Admin John Langston--02/25/14.	L 000		
L1106	19 CSR 30-30.060(1)(A)(3) Bylaws of the governing body shall Bylaws of the governing body shall require that an individual who complies with paragraph (1)(A)2.	L1106		

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L1106	Continued From page 1 of this rule shall be in charge in the absence of the administrator. This regulation is not met as evidenced by: Based on interview and policy review the facility failed to ensure that a policy was in place to designate the responsibilities and qualifications of an administrative designee when the administrator was absent from the facility. The facility did not conduct procedures at the time of the survey. Findings included: 1. During an interview on 06/11/13 at 10:30 AM Staff B, Director of Quality and Risk Management, stated that there is no policy which designated that a qualified person shall be in charge when the administrator is absent from the facility. 2. Review of the facility policy manual showed that no policy was in place to designate an individual to be in charge when the administrator was absent.	L1106		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on interview, and review of the Drug Enforcement Administration (DEA) and Bureau of Narcotics and Dangerous Drugs (BNDD) websites, the facility failed to maintain a DEA and a BNDD license. The facility did not conduct	L1111		

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COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1111	Continued From page 2 procedures at the time of the survey. Findings included: 1. Review of the DEA website, http://www.deadiversion.usdoj.gov/drugreg/faq.htm#4 showed: - A separate registration is required for each principal place of business or professional practice where controlled substances are stored, administered, or dispensed by a person. 2. Review of the Missouri BNDD website, http://health.mo.gov/safety/bndd/faqs.php#1 showed: - Any person, business, or entity in Missouri that wants to conduct any activities with controlled substances must have a registration. - A separate registration is required at each separate location where controlled substances are stocked and stored. 3. During an interview on 06/10/13 at 2:00 PM, Staff C, Heath Center Manager, stated that patients were prescribed and/or administered Valium (a controlled substance > a drug or chemical whose manufacture, possession, or use is regulated by a government) prior to surgical abortions when the procedures had been conducted at the facility.	L1111		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from	L1128		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1128	Continued From page 3 other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on interview, the facility failed to maintain an instruction manual from the manufacturer for the sterilizer used in the facility. The facility did not conduct procedures at the time of the survey. Findings included: During an interview on 06/11/13 at 3:00 PM, Staff G, Acting Administrator, Director of Health Center Operations, stated: - The facility did not have the original instruction manual for the sterilizer used at the facility, due to the age of the sterilizer; and - She had requested an instruction manual from the manufacturer following the surveyor's request to review the manual on 06/10/13.	L1128		
L1130	19 CSR 30-30.060(1)(B)(10) The facility shall have policies The facility shall have policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry. The facility may provide laundry services at the facility or utilize contract services. This regulation is not met as evidenced by: Based on interview and observation the facility	L1130		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1130	Continued From page 4 failed to ensure that clean linens were processed and stored separately from the processing of soiled linens. The facility did not conduct procedures at the time of the survey. Findings included: 1. Observation on 06/11/13 at 10:00 AM showed that in a room next to the laboratory were a clothes washer and dryer next to each other. On an open shelf in this room were an uncovered stack of approximately six patient gowns and three blankets. 2. During an interview on 06/11/13 at 10:00 AM Staff A, Licensed Practical Nurse, stated that he/she processed the laundry for the facility and the patient gowns were kept on the open shelf. The soiled linen was handled in this room before being placed in the clothes washer. Staff A stated that the facility did not have patients for abortion procedures but the processing and storage of the linen remained the same as when they had patients for these procedures.	L1130		
L1169	19 CSR 30-30.060(3)(I) An emergeny tray equipped to treat An emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest and cardiac arrest shall be immediately available to the procedure room and recovery room. This regulation is not met as evidenced by: Based on interview, the facility failed to maintain working batteries for the Automated External Defibrillator (AED) unit (a device that sends an electric shock to the heart that will restore the	L1169		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1169	Continued From page 5 natural heart rhythm to the victim during a cardiac arrest) that was to be kept on the facility crash cart. The facility did not conduct procedures at the time of the survey. Findings included: During an interview on 06/11/13 at 11:00 AM, Staff G, Acting Administrator, Director of Health Center Operations, stated that the AED unit needed replacement batteries and had recently ordered batteries.	L1169		
L1241	19 CSR 30-30.070(3)(A) Smoke detectors shall be located in all Smoke detectors shall be located in all rooms and in corridors at thirty-feet (30') intervals unless the building is rated Type II (222) fire-resistive or if it is a one (1)-story building rated Type II (111) protected-noncombustible as described in Standard on Types of Building Construction 1979 published by the NFPA. If the building is multistoried and rated combustible, it shall be protected throughout by an approved automatic sprinkler system; This regulation is not met as evidenced by: Based on observation and interview the facility failed to ensure that all smoke detectors required to be installed in the facility received routine testing to ensure proper operation annually. The facility did not conduct procedures at the time of the survey. Findings included: 1. Observation on 06/10/13 and 06/11/13 of the corridors and habitable areas of the facility	L1241		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1241	Continued From page 6 showed that a smoke detectors were present in all areas. 2. During an interview on 06/11/13 at 12:15 PM Staff C, manager, stated that he/she knew of no test or inspection that had ever been done for the smoke detectors to ensure that they functioned properly.	L1241		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 02/25/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments UPDATE 02/25/2014. This facility was found to be NOT performing abortion procedures. As they were not performing the procedure that required a license (and had no immediate plans to do so), a new license was not provided. Discussions were started between PP and DHSS regarding this process, with PP wishing to retain some semblance of the license, if for no other reason, so that if and when they ever reopened the facilty to perform abortions, the 2010 settlement agreement on the physical standards would still be in place. In general, DHSS was OK with this, and discussion about an additional amendment to the settlement agreement continued (we "close" the license with the agreement that a future provider [at the same location] would still have the relaxed construction standards in place from 2010. However, as of Feb 2014, there seems to have been no further movement toward an additional settlement agreement. A license has NOT been generated, nor will it be for the foreseeable future. An SOD for the June 2013 survey was never issued. This SOD and related survey processes have been held up since that time. After discussion with Section Administrator Dean Linneman, it was decided to officially close the file on both the facility and the 2013 survey of PP. (Pending a later reversal by OGC). --BAC Admin John Langston--02/25/14.	{L 000}		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 3, 2015

Vicki Casey (Vicki.Casey@ppkm.org)
Columbia Center, Planned Parenthood of Kansas and Mid-Missouri
711 N. Providence Rd
Columbia, MO 65203

Re: Initial Licensure Survey

Dear Ms. Casey:

An onsite initial licensure survey for your facility to provide abortion services began on 04/02/2015. The facility was found **not** to be in compliance with all regulatory requirements as described in 19 CSR 30-30.060 and 19 CSR 30-30.070. As a result, a license will **not** be issued until the following items have each been adequately addressed:

1. A check of all current employees to ensure that none appear on the Employee Disqualification List (EDL) maintained by the Department of Health and Senior Services as required for all facilities licensed under chapter 197 must be completed. Further, a method and policy to ensure that any new employee has this check done before hire and that the facility periodically checks the EDL for all employees must be in place.

2. Ensure that all physicians on the medical staff providing abortion services have received a complete credentialing packet to include: a)appointment and approval by the Governing Body; b)appropriate certificates for medications; c)approval of privileges; and d)a completed application to be on staff at the facility.

3. The facility will need appropriate certificates for medications via registration for Controlled Substances from the Bureau of Narcotics & Dangerous Drugs and the Drug Enforcement Agency (DEA).

4. The facility will need to submit a waiver/variance request for the provision of 19 CSR 30-30.070 (2)(N) which requires to be sized to accommodate at least four (4) recovery beds or recliners for each procedure room. Required space necessary is not available and facility staff indicated two (2) is sufficient for planned licensed services and workload.

5. The Facility initially plans to offer only medication-induced procedures, but to expand to surgical procedures later in the summer. As the equipment for surgical procedures has not been purchased and is not onsite, the facility is not currently prepared to provide the surgical services. BAC will need to revisit prior to permitting surgical procedures. Therefore, the license, when issued, will only approve the facility for medication-induced procedures. Please acknowledge in your written response your facility understands this limitation placed on your license.

Sincerely,

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	04/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L 000	Initial Comments Findings letter issued 4/3/15 instead of SoD. See file for letter. Survey closed 7/15/15.	L 000		

Missouri Department of Health and Senior Services
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

05/01/2015

RECEIVED MAY 07 2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: PRIDGEON, KIMBERLY DAWN
Registrant Number: 62779590

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 05/01/2015. The background screening, confirmation #116971850573, conducted on 05/01/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

The FCSR provides background screening information for employment purposes only. Any person who uses the information obtained from the registry for any purpose other than that specifically provided for in sections 210.900 to 210.936 is guilty of a class B misdemeanor, RSMo §210.921.3. The FCSR bases criminal history identification on the name, Social Security number and date of birth provided by the inquirer, not by the use of fingerprints. Please be advised that you must contact your licensing representative or other agency contact to determine whether this background screening meets state agency requirements for licensure, certification or registration. If you have questions or need assistance, you may contact the FCSR's toll free call center at 866-422-6872, or visit our Internet site at http://health.mo.gov/safety/fcsr/.

RECEIVED JUN - 1 2015

Planned Parenthood®
Care. No matter what.

Comprehensive Health of Planned Parenthood of Kansas and Mid-Missouri

CORPORATE BOARD RESOLUTION

Approval of Appointment of Medical Staff

I HEREBY CERTIFY that at a meeting of the Board of Directors of **Comprehensive Health of Planned Parenthood of Kansas and Mid-Missouri (CHPPKM)**, a corporation organized and existing under and by virtue of the laws of the State of Missouri, held on the 12th day of May, 2015, at which said meeting a quorum was present and acting throughout, the following resolution was adopted and ever since has been and now is in full force and effect.

RESOLVED, the Board of Directors approves the appointment of Dr. Colleen McNicholas as a contract abortion provider at the meeting of CHPPKM's Board of Directors held on May 12, 2015.

In witness whereof, I have hereunto set my hand this 12th day of May, 2015.

Marjorie Sable
Board Secretary

Americans United for Life

To ensure that every individual has the knowledge, opportunity and freedom to make informed private decisions about reproductive and sexual health.

Missouri Department of Health and Senior Services
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: WINDHAM, EMMA ANN
Registrant Number: 64955877

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562621, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

The FCSR provides background screening information for employment purposes only. Any person who uses the information obtained from the registry for any purpose other than that specifically provided for in sections 210.900 to 210.936 is guilty of a class B misdemeanor, RSMo §210.921.3. The FCSR bases criminal history identification on the name, Social Security number and date of birth provided by the inquirer, not by the use of fingerprints. Please be advised that you must contact your licensing representative or other agency contact to determine whether this background screening meets state agency requirements for licensure, certification or registration. If you have questions or need assistance, you may contact the FCSR's toll free call center at 866-422-6872, or visit our Internet site at http://health.mo.gov/safety/fcsr/.

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Director

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Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: MCNICHOLAS, COLLEEN
Registrant Number: 64495533

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/28/2015. The background screening, confirmation #116971561995, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: CASEY, VICKI LYNN
Registrant Number: 14258538

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562691, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: WARD, MARIA LUISA
Registrant Number: 64955830

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562747, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: WILSON, KRISTIN L
Registrant Number: 64955883

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562832, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

The FCSR provides background screening information for employment purposes only. Any person who uses the information obtained from the registry for any purpose other than that specifically provided for in sections 210.900 to 210.936 is guilty of a class B misdemeanor, RSMo §210.921.3. The FCSR bases criminal history identification on the name, Social Security number and date of birth provided by the inquirer, not by the use of fingerprints. Please be advised that you must contact your licensing representative or other agency contact to determine whether this background screening meets state agency requirements for licensure, certification or registration. If you have questions or need assistance, you may contact the FCSR's toll free call center at 866-422-6872, or visit our Internet site at http://health.mo.gov/safety/fcsr/.

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

04/28/2015

FAMILY CARE SAFETY REGISTRY
Background Screening Results - Inquirer
Registrant: OWENS, KORI LYNN
Registrant Number: 62380544

PLANNED PARENTHOOD OF KANSAS & MID-MISSOURI
ATTN: MONICA KAYE
4401 W 109TH ST STE 200
OVERLAND PARK, KS 66211

The Family Care Safety Registry (FCSR) received your request for a background screening on 04/27/2015. The background screening, confirmation #116971562796, conducted on 04/28/2015, indicated the following:

No finding reported in the background screening.

The results above were confirmed by searching the following state databases that contain Missouri data only, using the above registrant's name, date of birth and Social Security number:

- Criminal history records maintained by the MO State Highway Patrol
- Sex Offender Registry records maintained by the MO State Highway Patrol
- Child abuse/neglect records maintained by the MO Department of Social Services
- Foster parent licensure records maintained by the MO Department of Social Services
- Child care licensure records maintained by the MO Department of Health and Senior Services
- Employee Disqualification List maintained by the MO Department of Health and Senior Services
- Employee Disqualification Registry maintained by the MO Department of Mental Health

A copy of this background screening has been provided to the individual registrant. If finding(s) were indicated, you may obtain specific information about these results by contacting the FCSR toll free at 866-422-6872, or by submitting your request in writing to the Missouri Department of Health and Senior Services, Family Care Safety Registry, PO Box 570, Jefferson City, MO, 65102. The request must be signed and must include your name, address, telephone number, the reason for requesting the information, the registrant's full name and Social Security number, and the confirmation number from the first paragraph above.

The FCSR provides background screening information for employment purposes only. Any person who uses the information obtained from the registry for any purpose other than that specifically provided for in sections 210.900 to 210.936 is guilty of a class B misdemeanor, RSMo §210.921.3. The FCSR bases criminal history identification on the name, Social Security number and date of birth provided by the inquirer, not by the use of fingerprints. Please be advised that you must contact your licensing representative or other agency contact to determine whether this background screening meets state agency requirements for licensure, certification or registration. If you have questions or need assistance, you may contact the FCSR's toll free call center at 866-422-6872, or visit our Internet site at http://health.mo.gov/safety/fcsr/.

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	COMPREHENSIVE HEALTH OF PPKM (COMPREHENSIVE HEALTH OF PPKM)
BNDD Number:	2500027602
Description:	AMBULATORY SURGICAL CENTER
Street Address:	711 N PROVIDENCE RD
City/State/Zip:	COLUMBIA, MO 65203.4357
Phone Number:	573-875-4177
Registration Effective:	4/28/2015
Registration Expires:	4/30/2016
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	4/28/2015

Validation Date of the Registration is: 4/30/2015

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

COMPREHENSIVE HEALTH OF PPKM
711 N PROVIDENCE RD
COLUMBIA, MO 65203-0000-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC5215428	08-31-2018	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	HOSPITAL/CLINIC	05-11-2015

COMPREHENSIVE HEALTH OF PPKM
711 N PROVIDENCE RD
COLUMBIA, MO 65203-0000

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC5215428	08-31-2018	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	HOSPITAL/CLINIC	05-11-2015

COMPREHENSIVE HEALTH OF PPKM
711 N PROVIDENCE RD
COLUMBIA, MO 65203-0000

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223 (4/07)

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

APPLICATION FOR EMPLOYMENT

Colleen McNicholas DO

APPLICANT NAME

APPLICATION FOR EMPLOYMENT

Planned Parenthood of Kansas and Mid-Missouri is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, age, gender, sexual orientation, national origin, ancestry, disability, citizenship, genetic information, veteran service or status or any other characteristic protected under Federal or State law.

This application shall be considered active for a period not to exceed ***45 days***. Any applicant wishing to be considered for employment beyond this time period should complete another application at the end of that period.

Personal Information

Name (Last, First, Middle)	**E-Mail Address**	**Date of Application**
Click here to enter text. McNicholas, Colleen	mcnicholasc@wudosis.wush.edu	05/29/15

Have you ever worked under another name? If so, supply: Click here to enter text.	**Telephone Number with Area Code**
No	Click here to enter text. 314-747-6721

Current Address: Street	**City**	**State**	**Zip**	**Number of Years**
4533 Clayton Ave	St Louis	MO	63110	4

Past 7 Years Residency

Address: Street	**City**	**State**	**Zip**	**Number of Years**
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Address: Street Click here to enter text.	**City** Click here to enter text.	**State** Click here to enter text.	**Zip** Click here to enter text.	**Number of Years** Click here to enter text.
Address: Street Click here to enter text.	**City** Click here to enter text.	**State** Click here to enter text.	**Zip** Click here to enter text.	**Number of Years** Click here to enter text.
Address: Street Click here to enter text.	**City** Click here to enter text.	**State** Click here to enter text.	**Zip** Click here to enter text.	**Number of Years** Click here to enter text.

Are you available to work:	**Number of Hours:** Negotiable	**Date Available** 6/5/2015
☐**Full-Time** XPart-Time		

Position Applying for: ***(Check all that apply)*** ☐CMA ☐RN/LPN ☐Administrative ☐Health Center Manager
Other __Physician_____

Location: ☐ Overland Park ☐Wichita ☐North Kansas City XColumbia ☐Independence ☐ South Kansas City ☐Patty Brous
Other

Salary Requirements	**Days Available:** X Mon ☐ Tues X Wed ☐Thurs ☐ Fri ☐ Sat ☐ Sun	**Are you currently employed?** XYes ☐ No **If Yes, can we contact them?** XYes ☐ No
Click here to enter text. /Hour N/A Click here to enter text. /Year N/A		

How did you hear about Planned Parenthood of Kansas and Mid-Missouri or this position? Click here to enter text.

General Information

Have you been convicted of a felony within the last seven years? ☐ **Yes** X **No**
If yes, please describe: Click here to enter text.

Note: A conviction record is not an automatic bar to employment. A conviction will be considered only in relation to specific job requirements. An applicant shall be notified if an adverse decision was based on conviction data.

Training and Skills

List special Skills, Proficiencies or experiences which you feel may especially qualify you for the position for which you are applying: Click here to enter text.

EDUCATION AND HISTORY

Name	Location and Telephone	Course	Years Completed Degree
High School/GED Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Undergraduate Benedictine University	Lisle ILL	Forensic Chemistry	Bachelor of Science
Graduate Kirksville College of Osteopathic Medicine	Kirksville MO	Osteopathic Medicine	Doctor of Osteopathy
Post Graduate Atlanta Medical Centers Washington University	Atlanta GA ST Louis MO	Internship Residency	

WORK EXPERIENCE – STARTING WITH MOST RECENT

Name of Employer Washington University	**4533 Clayton Avenue** **St Louis MO 63110**	**Date Employed** **From:** 2009 **To:** Current
Telephone of Employer 314-747-6721	**Supervisor's Name and Title** Click here to enter text. Jeffery Peipert	**Rate of Pay:** N/A
Position or Title Doctor of Osteopathy	**Reason for Leaving** N/A	
Description of Duties:		

NEXT PREVIOUS EMPLOYER

Name of Employer DuPage County Coroner's Office	**Address of Employer** **Carol Stream IL**	**Date Employed** **From:** 1999 **To:** 2003
Telephone of Employer Click here to enter text.	**Supervisor's Name and Title** Click here to enter text.	**Rate of Pay:** Click here to enter text.
Position or Title Pathology Assistant	**Reason for Leaving** Graduate School	
Description of Duties: Assisted with autopsy, organ harvesting and toxicology samples		

NEXT PREVIOUS EMPLOYER

Name of Employer Benedictine University	**Address of Employer** **Lisle, IL**	**Date Employed** **From:** 2002 **To:** 2002
Telephone of Employer Click here to enter text.	**Supervisor's Name and Title** Click here to enter text.	**Rate of Pay:** Click here to enter text.
Position or Title Cell Biology Researcher	**Reason for Leaving** Graduate School	
Description of Duties: Lab animal care, tissue culture, preparation and maintenance of cell lines, media preparation		

WORK RELATED REFERENCES
(Provide at least 3)
Please note that family and friends are not considered relevant employment references.

Name of Contact PPSLR – Mary Kogut	**Period Known** **From:** 2012 **To:** Current
Contact Telephone Number 314-531-7526	**Mailing Address** 4251 Forest Park Ave St Louis MO 63108
Contact Email Address	
How did you know this individual: Currently Employed	

WORK RELATED REFERENCES

Name of Contact Click here to enter text. Tessa Madden	**Period Known** **From:** 2011 **To:** Current
Contact Telephone Number 314-747-6721	**Mailing Address** 4533 Clayton Ave St Louis MO 63110
Contact Email Address Click here to enter text. maddent@wustl.edu	
How did you know this individual: Click here to enter text. college	

WORK RELATED REFERENCES

Name of Contact Click here to enter text. David Eisenberg	**Period Known** **From:** Click here to enter a date. 2011 **To:** Click here to enter a date. Current
Contact Telephone Number Click here to enter text. 314-747-1331	**Mailing Address** Click here to enter text.
Contact Email Address Click here to enter text. eisenbergd@wustl.edu	
How did you know this individual: Click here to enter text. Colleague	

Work Related Reference

Name of Contact Click here to enter text.	**Period Known** **From:** Click here to enter a date. **To:** Click here to enter a date.
Contact Telephone Number Click here to enter text.	**Mailing Address** Click here to enter text.
Contact Email Address Click here to enter text.	
How did you know this individual: Click here to enter text.	

Americans United for Life

READ CAREFULLY BEFORE SIGNING BELOW
(Signature required in order to be considered for employment.)

1. I understand that Planned Parenthood of Kansas and Mid-Missouri will consider any requests for accommodations of physical or mental disabilities by an otherwise qualified person at any time before or after employment begins. I understand that the company would appreciate as much advance notice as possible regarding request for accommodation, and that documentation of the need for accommodation might be required.

2. I understand that I may be required to pass a drug screen. Successful completion of this test is a condition of employment. I further understand that I, as all Planned Parenthood of Kansas and Mid-Missouri employees, am subject to ongoing drug testing program and will be required to pass such tests as a condition of continued employment.

3. I understand that a background investigation including my employment and criminal history will be performed as a condition of employment; I hereby authorize Planned Parenthood of Kansas and Mid-Missouri and or its agents to thoroughly request, receive and verify all statements and information contained in my application or resume and as relevant to this background investigation. I release Planned Parenthood of Kansas and Mid-Missouri from all liability for any damages that may result from doing so. I authorize any persons or organizations referenced in this application, including but not limited to employers, educational institutions, licensing agencies, law enforcement agencies, financial institutions, government agencies, courts, and other persons or organizations to give you any and all information concerning my previous employment, education, or any other information they might have, personal or otherwise, with regard to any of the subjects covered by this application. I release all such parties from all liability for any damages that may result from furnishing such information to Planned Parenthood of Kansas and Mid-Missouri.

4. I understand that employment is contingent upon my complying with the employment verification requirements of the Immigration Reform and Control Act.

5. I certify that I personally completed this application and that the information provided in this application (and accompanying resume, if any) is true and complete. I understand that any misstatement, falsification, omission or misrepresentation on this application or in any interview is grounds for refusal to hire, or if I am hired and the same is discovered thereafter, I will be separated. I understand that all information provided by me on this application or in any interview is subject to verification.

6. I acknowledge that if I am employed by the company, my employment will be at-will, that I will be required to follow all rules and regulations of the company and that my employment may be terminated with or without cause, with or without notice, at the option of myself or the company. No one other than the President has the authority to enter into any agreement for employment for any specified period of time or to make any agreement contrary to the foregoing, either before commencement of employment or after I have become employed.

7. I certify that I have read or have had read to me, items 1, 2, 3, 4, 5 and 6 above. I understand the contents and hereby acknowledge receipt and understanding of this information. Further, I confirm that I desire to be considered for employment under these conditions.

Click here to enter text.

Signature of Applicant

5/29/2015

Date

Americans United for Life

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

CONSUMER DISCLOSURE AND AUTHORIZATION FORM

Disclosure Regarding Background Investigation

Planned Parenthood of Kansas and Mid-Missouri (the "Company") may request, for lawful employment purposes, background information about you from a consumer reporting agency in connection with your employment or application for employment (including independent contractor assignments, as applicable). This background information may be obtained in the form of consumer reports and/or investigative consumer reports (commonly known as "background reports"). An "investigative consumer report" is a background report that includes information from personal interviews (except in California, where that term includes background reports with or without information obtained from personal interviews), the most common form of which is checking personal or professional references. These background reports may be obtained at any time after receipt of your authorization and, if you are hired or engaged by the Company, throughout your employment or your contract period, as allowed by law.

HireRight, Inc. ("HireRight"), or another consumer reporting agency, will prepare or assemble the background reports for the Company. HireRight is located and can be contacted by mail at 5151 California, Irvine, CA 92617, and HireRight can be contacted by phone at (800) 400-2761. Information about HireRight's privacy practices is available at www.hireright.com/Privacy-Policy.aspx.

The background report may contain information concerning your character, general reputation, personal characteristics, mode of living, and credit standing. The types of information that may be obtained include, but are not limited to: social security number verifications; address history; credit reports and history; criminal records and history; public court records; driving records; accident history; worker's compensation claims; bankruptcy filings; educational history verifications (e.g., dates of attendance, degrees obtained); employment history verifications (e.g., dates of employment, salary information, reasons for termination, etc.); personal and professional references checks; professional licensing and certification checks; drug/alcohol testing results, and drug/alcohol history in violation of law and/or company policy; and other information bearing on your character, general reputation, personal characteristics, mode of living and credit standing.

This information may be obtained from private and public record sources, including, as appropriate: government agencies and courthouses; educational institutions; former employers; and, for investigative consumer rep01ts, personal interviews with sources such as neighbors, friends, former employers and associates; and other information sources. If the Company should obtain information bearing on your credit worthiness, credit standing or credit capacity for reasons other than as required by law, then the Company will use such credit information to evaluate whether you would present an unacceptable risk of theft or other dishonest behavior in the job for which you are being evaluated.

You may request more information about the nature and scope of an investigative consumer report, if any, by contacting the Company.

A summary of your rights under the Fair Credit Reporting Act, as well as certain state-specific notices, are also being provided to you.

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

AUTHORIZATION of BACKGROUND INVESTIGATION

I have carefully read and understand this Disclosure and Authorization form and the attached summary of rights under the Fair Credit Reporting Act. By my signature below, I consent to preparation of background reports by a consumer rep01ting agency such as HireRight, Inc. ("HireRight"), and to the release of such background reports to the Company and its designated representatives and agents, for the purpose of assisting the Company in making a determination as to my eligibility for employment (including independent contractor assignments, as applicable), promotion, retention or for other lawful employment purposes. I understand that if the Company hires me or contracts for my services, my consent will apply, and the Company may, as allowed by law, obtain additional background reports pertaining to me, without asking for my authorization again, throughout my employment or contract period from HireRight and/or other consumer reporting agencies.

I understand that information contained in my employment or contractor application, or otherwise disclosed by me before or during my employment or contract assignment, if any, may be used for the purpose of obtaining and evaluating background reports on me. I also understand that nothing herein shall be construed as an offer of employment or contract for services.

I hereby authorize all of the following, without limitation, to disclose information about me to the consumer reporting agency and its agents: law enforcement and all other federal, state and local agencies, learning institutions (including public and private schools, colleges and universities), testing agencies, information service bureaus, credit bureaus, record/data repositories, courts (federal, state and local), motor vehicle records agencies, my past or present employers, the military, and all other individuals and sources with any information about or concerning me. The information that can be disclosed to the consumer reporting agency and its agents includes, but is not limited to, information concerning my employment and earnings history, education, credit history, motor vehicle history, criminal history, military service, professional credentials and licenses.

By my signature below, I also certify the information I provided on and in connection with this form is true, accurate and complete. I agree that this form in original, faxed, photocopied or electronic (including electronically signed) form; will be valid for any background reports that may be requested by or on behalf of the Company.

Applicant Name: **Last** Click here to enter text. **First** Click here to enter text. **Middle** Click here to enter text.

Applicant Signature

5/29/2015
Date

Americans United for Life

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

Para informacion en espaiiol, visite www.consumerfinance.gov/leammore o escribe a Ia ConsumerFinancial Protection Bureau, 1700 G Street N.W., Washington DC 20552.

A SUMMARY OF YOUR RIGHTS UNDER THE FAIR CREDIT REPORTINGACT

The federal Fair Credit Reporting Act (FCRA) promotes the accuracy, fairness, and privacy of information in the files of consumer reporting agencies. There are many types of consumer rep01ting agencies, including credit bureaus and specialty agencies (such as agencies that sell inf01mation about check writing histories, medical records, and rental history records). Here is a summary of your major rights under the FCRA. For more information, including information about additional rights, go to www.consumerfinance.gov/learnmore or write to: Consumer Financial Protection Bureau, 1700 G Street N.W., Washington, DC 20552.

- You must be told if information in your file has been used against you. Anyone who uses a credit report or another type of consumer report to deny your application for credit, insurance, or employment - or to take another adverse action against you - must tell you, and must give you the name, address, and phone number of the agency that provided the information.
- You have the right to know what is in your file. You may request and obtain all the information about you in the files of a consumer reporting agency (your "file disclosure"). You will be required to provide proper identification, which may include your Social Security number. In many cases, the disclosure will be free. You are entitled to a free file disclosure if:
    - a person has taken adverse action against you because of information in your credit report;
    - you are the victim of identity theft and place a fraud alert in your file;
    - your file contains inaccurate information as a result of fraud;
    - you are on public assistance;
    - you are unemployed but expect to apply for employment within 60 days.
- In addition, all consumers are entitled to one free disclosure every 12 months upon request from each nationwide credit bureau and from nationwide specialty consumer rep01ting agencies. See www.consumerfinance.gov/learn more for additional information.
- You have the right to ask for a credit score. Credit scores are numerical summaries of your creditworthiness based on information from credit bureaus. You may request a credit score from consumer reporting agencies that create scores or distribute scores used in residential real property loans, but you will have to pay for it. In some mortgage transactions, you will receive credit score information for free from the mortgage lender.
- You have the right to dispute incomplete or inaccurate information. If you identify information in your file that is incomplete or inaccurate, and report it to the consumer reporting agency, the agency must investigate unless your dispute is frivolous. See www.consumerfinance.gov/learnmore for an explanation of dispute procedures.
- Consumer reporting agencies must correct or delete inaccurate, incomplete, or unverifiable information. Inaccurate, incomplete or unverifiable information must be removed or corrected, usually within 30 days. However, a consumer reporting agency may continue to report information it has verified as accurate.
- Consumer reporting agencies may not report outdated negative information. In most cases, a consumer reporting agency may not report negative information that is more than seven years old, or bankruptcies that are more than 10 years old.
- Access to your file is limited. A consumer reporting agency may provide information about you only to people with a valid need-- usually to consider an application with a creditor, insurer, employer, landlord, or other business. The FCRA specifies those with a valid need for access.
- You must give your consent for reports to be provided to employers. A consumer reporting agency may not give out information about you to your employer, or a potential employer, without your written consent given to the employer. Written consent generally is not required in the trucking industry. For more information, go to www.consumerfinance.gov/learnmore.
- You may limit "prescreened" offers of credit and insurance you get based on information in your credit report. Unsolicited "prescreened" offers for credit and insurance must include a toll-free phone number you can call if you choose to remove your name and address from the lists these offers are based on. You may opt-out with the nationwide credit bureaus at 1-888-567-8688.

- You may seek damages from violators. If a consumer reporting agency, or, in some cases, a user of consumer reporter or a furnisher of information to a consumer reporting agency violates the FCRA, you may be able to sue in state or federal court.
- Identity theft victims and active duty military personnel have additional rights. For more information, visit www.consumerfinance.gov/learnmore .

States may enforce the FCRA, and many states have their own consumer reporting laws. In some cases, you may have more rights under state law. For more information, contact your state or local consumer protection agency or your state Attorney General. For Information about your Federal rights contact:

QUESTIONS OR CONCERNS

States may enforce the FCRA, and many states have their own consumer reporting laws. In some cases, you may have more rights under state law. For more information, contact your state or local consumer protection agency or your state Attorney General. For information about your federal rights, contact:

TYPE OF BUSINESS:	CONTACT:
1. a. Banks, savings associations, and credit unions with total assets of over $10 billion and their affiliates. b. Such affiliates that are not banks, savings associations, or credit unions also should list, in addition to the Bureau:	a. Bureau of Consumer Financial Protection 1700 G Street NW Washington, DC 20006 b. Federal Trade Commission: Consumer Response Center – FCRA Washington, DC 20580 (877) 382-4357
2. To the extent not included in item 1 above: a. National banks, federal savings associations, and federal branches and federal agencies of foreign banks b. State member banks, branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act c. Nonmember Insured Banks, Insured State Branches of Foreign Banks, and insured state savings associations d. Federal Credit Unions	a. Office of the Comptroller of the Currency Customer Assistance Group 1301 McKinney Street, Suite 3450 Houston, TX 77010-9050 b. Federal Reserve Consumer Help Center P.O. Box 1200 Minneapolis, MN 55480 c. FDIC Consumer Response Center 1100 Walnut Street, Box #11 Kansas City, MO 64106 d. National Credit Union Administration Office of Consumer Protection (OCP) Division of Consumer Compliance & Outreach DCCO) Alexandria, VA 22314
3. Air carriers	Asst. General Counsel for Aviation Enforcement & Proceedings Department of Transportation 400 Seventh Street SW, Washington, DC 20590
4. Creditors Subject to Surface Transportation Board	Office of Proceedings, Surface Transportation Board Department of Transportation 1925 K Street NW, Washington, DC 20423
5. Creditors Subject to Packers and Stockyards Act	Nearest Packers and Stockyards Administration area supervisor
6. Small Business Investment Companies	Associate Deputy Administrator for Capital Access United States Small Business Administration 406 Third Street, SW, 8th Floor, Washington, DC 20416
7. Brokers and Dealers	Securities and Exchange Commission 100 F St NE, Washington, DC 20549
8. Federal Land Banks, Federal Land Bank Associations, Federal Intermediate Credit Banks, and Production Credit Associations	Farm Credit Administration 1501 Farm Credit Drive, McLean, VA 22102-5090
9. Retailers, Finance Companies, and All Other Creditors Not Listed Above	FTC Regional Office for region in which the creditor operates or Federal Trade Commission: Consumer Response Center – FCRA Washington, DC 20580 (877) 382-4357

PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

CONSENT AND RELEASE FOR SUBSTANCE TESTING

I understand that the purpose of the Substance Abuse policy is to provide a safe working environment. Accordingly, I understand that as a condition of employment with Planned Parenthood of Kansas and Mid-Missouri, I will be required to undergo substance testing. I also understand that a positive drug/alcohol test may exclude me from employment. I further understand that I am also subject to ongoing testing requirement under the company policy. In addition, I understand that a positive substance test at any time during my employment with Planned Parenthood of Kansas and Mid-Missouri may be cause for dismissal.

I hereby consent to substance testing as required by Planned Parenthood of Kansas and Mid-Missouri. I further authorize the release of all information and records, including test results of the screening or testing to Planned Parenthood of Kansas and Mid-Missouri.

I hereby release Planned Parenthood of Kansas and Mid-Missouri from any and all claims arising from the administration of such tests.

I have read and understand this consent and release form, and have signed it voluntarily.

Print Name: Click here to enter text.

Signature:

Date: 5/29/2015

Americans United for Life

CURRICULUM VITAE
Colleen Patricia McNicholas, D.O.

Date: February 2011

Personal Information:

Sex:	Female
Date of Birth:	December 10, 1980
Place of Birth:	Chicago, IL

Citizenship: United States of America

Address and Telephone Numbers:

Hospital:
Department of Obstetrics and Gynecology
Washington University in St. Louis
Campus Box 8064
4911 Barnes-Jewish Hospital Plaza
Saint Louis, Missouri 63110-1094

Home:
3339 Wisconsin Ave
Saint Louis, Missouri 63118

Present Position:
Resident, Department of Obstetrics and Gynecology
Washington University in Saint Louis
Barnes-Jewish Hospital

Education:

Undergraduate:	1998-2003	Benedictine University Lisle, Illinois B.S. Forensic Chemistry
Graduate:	2003-2007	Kirksville College of Osteopathic Medicine Kirksville, MO Doctor of Osteopathy
Postgraduate:	2007-2008	Atlanta Medical Centers Atlanta, Georgia Internship
	2008-current	Washington University in Saint Louis Residency

Employment:

1999-2003	***Pathology Assistant,*** Dupage County Coroner's Office, Carol Stream IL Assisted with autopsy, organ harvesting, and toxicology samples
2000-2002	***Cell Biology Researcher,*** Benedictine University, Lisle IL Lab animal care, tissue culture, preparation and maintenance of cell lines, media preparation, autoclave sterilization
2000-2002	***Student LabTech (Chemistry),*** Benedictine University, Lisle IL

Maintenance of chromatography equipment, stock solutions, and general lab care.

2009-current **Washington University School of Medicine gynecology clinical teaching**
Clinical instruction on pelvic and breast exam skills

Medical Licensure:

2007-current Missouri Temporary Medical License
#2008015965

Honors and Awards:

2006 *Presidents Award*: Women in Medicine
2003 *Senior Academic Award: College of Arts and Science*, Benedictine University
2002 *PGG Industries Foundation J Earl Burrell Scholarship*, Benedictine University
2001 *Gregory Snoke Memorial Scholarship*, Benedictine University
2001 *American Chemical Society Analytical Achievement Award*, Benedictine University
2001 *American Chemical Society Division of Analytical Chemistry 2001 Undergraduate Award*, Benedictine University

Editorial Responsibilities:

2009-current Reviewer, American Journal of Obstetrics and Gynecology

Professional Societies and Organizations:

2010-current ***Member***, Missouri Association of Osteopathic Physicians
2008-current ***Board Member***, St Louis Obstetrics and Gynecology Society
2007-current ***Member***, American Medical Association
2006-current ***Member***, Association of Reproductive Health Professionals
2006-current ***Member***, American College of Obstetrics and Gynecology
2006-current ***Member***, Gay and Lesbian Medical Association
2003-current ***Member***, Medical Students for Choice
2003-current ***Member***, American Osteopathic Association

Invited Presentations:

Sept 2010 Oral Presentation, Association of Reproductive Healthcare providers
Madden T, McNicholas CP, Secura GM, Allsworth JE, Zhao Q, Peipert JF. Rates of Expulsion and Continuation of Intrauterine Contraception at 12 months in Nulliparous and Adolescent Women

April 2010 Oral Presentation, Rothman Resident Research Day
McNicholas CP, Madden T, Secura GM, Allsworth JE, Zhao Q, Peipert JF. Rates of Expulsion and Continuation of Intrauterine Contraception at 12 months in Nulliparous and Adolescent Women

MCNICHOLAS, COLLEEN
REPRODUCTIVE HEALTH SERVICES OF PLANNED
4251 FOREST PARK AVE.
ST LOUIS, MO 63108-2810-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BM2743789	01-31-2017	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	PRACTITIONER	12-17-2013

MCNICHOLAS, COLLEEN
REPRODUCTIVE HEALTH SERVICES OF PLANNED
4251 FOREST PARK AVE.
ST LOUIS, MO 63108-2810

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

UNITED STATES DEPARTMENT OF JUSTICE
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Form DEA-223 (4/97)

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	MCNICHOLAS, COLLEEN P
BNDD Number:	53597417
Description:	MEDICAL DOCTOR
Street Address:	4251 FOREST PARK AVE
City/State/Zip:	ST LOUIS, MO 63108.2810
Phone Number:	314-531-7526
Registration Effective:	7/15/2014
Registration Expires:	7/31/2015
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	7/15/2014

Validation Date of the Registration is: 2/23/2015

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

Planned Parenthood®
of Kansas and Mid-Missouri

Clinical Privileges to Perform Ultrasound

Name of person requesting privileges: Colleen McNicholas

Previous experience or certifications in Ultrasound Services: >3yrs @ PPSLR

Trainee initials below:

CM 1. I have successfully completed the CAPS Ultrasound CD training and/or passed the test. Date completed: 4/1/15

_____ 2. During proctoring, I performed approximately _____ (number) sonograms (if applicable).

_____ 3. I am familiar with how to change the image characteristics on an ultrasound machine and basic troubleshooting techniques (enlarging, changing contrast).

_____ 4. I am able to perform the items checked below.

- ☑ Identify the uterus in pregnant and non-pregnant women
- ☑ Obtain images of uterus in early pregnancy in longitudinal and transverse planes
- ☑ Identify an intrauterine pregnancy
- ☑ Identify embryonic (fetal) pole and measure CRL (know formula 42 plus largest CRL)
- ☑ Identify gestational sac and measure mean sac size (know formula 30 plus mean gestational sac)
- ☑ Identify characteristics of normal and abnormal gestational sac
- ☑ Identify yolk sac
- ☑ Identify cardiac activity
- ☑ Identify multiple gestations (if seen during training)
- ☑ Identify normal sonographic findings following abortion (thickness of endometrial stripe)
- ☑ Identify BPD and measures BPD correctly
- ☑ Assure that patients are informed of their option to view the ultrasound image and of their option to be informed if there is a multiple pregnancy
- ☑ Able to document findings consistently and complete the ultrasound form correctly
- ☑ Recognize when findings require evaluation by physician

If applicable:

- ☑ Proficiency in performing ultrasound to identify intrauterine IUC
  - ☑ Paragard IUC ☑ Mirena IUC
- ☑ Proficiency in interpreting location (intrauterine placement) of IUC
  - ☑ Paragard IUC ☑ Mirena IUC

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For 2nd trimester privileging:
- [x] Femur length
- [x] Placental localization

Other Essential Proficiencies:
- [x] Provides appropriate patient information regarding procedure, its purpose and limitations
- [x] Queries/acknowledges patient's feelings around abortion decision and the ultrasound imaging procedure
- [x] Properly cleans, maintains equipment and disposes of contaminated supplies

[signature] 4/1/15
Signature of Trainee Date

The following staff person, _____, has been observed by the Program Director of Ultrasound Services or their designee, has proven proficiency in the above activities, and is granted privileges as below:

- [ ] First-trimester ultrasound targeted for medication or surgical abortion services
  - [ ] Performance of ultrasound
  - [ ] Interpretation of ultrasound
- [ ] Second trimester ultrasound targeted for surgical abortion services
  - [ ] Performance of ultrasound
  - [ ] Interpretation of ultrasound
- [ ] Localization of IUC
  - [ ] Performance of ultrasound (licensed health professional, certified sonographer only
  - [ ] Interpretation of ultrasound (clinician only – APC or physician)

[signature] ~~4/01/15~~ 04/01/15
Signature, Ultrasound Program Director or designee Date

Title

Americans United for Life

Training and Onboarding Requirements Checklist for Contract Physicians

Americans United for Life

Mandatory Reporting Roles and Responsibilities and Services to Minors Compliance (Parental Involvement/Consent)	HR 1. b & d, RC 3. a & b, MIN 1. d	Anyone in the following categories who has contact with clients or minors: full-time employees, part-time employees, per diem employees, independent contractors, volunteers, students and trainees. Exception: "hands-off" students/trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Managing Suspicious Encounters	HR 1. b & d LSS 3. b	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees. Exception: "hands-off" students/trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Ultrasound in Abortion Care	HR 3. k HR 4. l RQM 4 e	Anyone in the following categories who provides ultrasound services: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees. Exception: "hands-off" students/trainees.	[redacted]	~~Yet to be Completed~~ 4/1/15

Talking About Abortion	HR 3. j HR 4. h	Anyone in the following categories who talks to women about pregnancy options (including those who work in health centers that do not provide abortion on site): full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students, and trainees. Exception: "hands-off" students/trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Orientation to the Abortion Pill	HR 3. m HR 4. j	Anyone in the following categories who talks to clients about abortion (including those who do not provide abortion services) is required to complete modules one and two of this CAL course: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees. Module three is only required for licensed clinical staff (employees, volunteers, independent contractors, students and trainees) who assess for expected effects, side effects, complications, and completion of the procedure.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Affiliate-Wide Risk and Quality Management (RQM) Program	RQM 2. a HR 1. d	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	Update on PPKM Specific Policy 4/15/15 11/14/14
Fraud Risk Management	RQM 3. f	Full-time employees, part-time employees, and per diem employees, volunteers, and independent contractors.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Safety and Security Training	LSS 2. c	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	met with Director of Security PPKM 3/13/15

Medical Record Policies and Documentation	MR 1 MR 2	Anyone in the following categories who works in health centers and/or has contact with medical records: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Medical Standards and Guidelines Protocol Changes	CS 3. b	Anyone in the following categories who works in health centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	Reviewed access to MS&G @ PPKM 4/15/15 11/14/14
Intimate Partner Violence (IPV) and Reproductive Coercion	RC 3	Anyone in the following categories who works in health centers or education programs: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Productivity Goals and Practices	FH-BO 2.	Anyone in the following categories who works in the health centers and call centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☒ Training does not apply to this contracted physician ☐ Training was completed elsewhere (specify where)	
HIPAA Privacy and Security	RC 4. c RC 5. c	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	Met with Director of Security of PPICM 3/18/15
Customer Service Practices and Goals	FH-BO 4.	Anyone in the following categories who works in the health centers and call centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☒ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14

-OSHA Regulations	MPP 5. RC 1. a	Anyone in the following categories who works in the health centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
CLIA Regulations	MPP 6.	Anyone in the following categories who works in the health centers: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Clinical Staff Orientation	OTE 3.	Anyone in the following categories who works in the health centers and call centers: full-time employees, part-time employees, per diem employees, independent contractors.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Pharmaceuticals (Preparation and Provision of Medications)	CS 4	Anyone in the following categories involved in the preparation and provision of medications: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14
Board Governance & Fiduciary Responsibilities	BD 3. b	All volunteers who serve on the affiliate board of directors and/or the budget and finance committee.	Choose one: ☐ Training was completed at affiliate ☒ Training does not apply to this contracted physician ☐ Training was completed elsewhere (specify where)	
Human Resources Training on Diversity and Cultural Competency in the Workplace	HR 2. c	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PPSLR	11/14/14

501(c)(3) and 501(c)(4) Non-Profit Organization Allowable Guidelines	PA 1. e	Anyone in the following categories who is involved with public affairs, development and finance: full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	Choose one: ☐ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☒ Training was completed elsewhere (specify where) PHSU	11/19/14
Safety and Security Drills	LSS 2. m	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	☒ Site-specific briefing given by affiliate	4/15/15
Fire Drills	LSS 2. k	Full-time employees, part-time employees, per diem employees, volunteers, independent contractors, students and trainees.	☒ Site-specific briefing given by affiliate	4/15/15
Medical Emergency Drills	MMP 4. f OTE 3. f	Anyone in the following categories who works in health centers: full-time employees, part-time employees, per diem employees, independent contractors.	Choose one: ☒ Training was completed at affiliate ☐ Training does not apply to this contracted physician ☐ Training was completed elsewhere(specify where)	4/15/15

We confirm that Colleen McNicholas *an independent contractor, has completed all required trainings that pertain to his/her contracted function(s).*

Contracted Physician — Date 4/28/15

Human Resources — Date

Medical Director — Date 04/04/2015

This checklist should be in the contract provider's personnel file. During an accreditation review, all contract physician files will be included in the personnel file audit.

CLINICIAN SKILLS CHECKLIST: PROCTORING FORM

Name/Title: Colleen McNicholas Date of Hire: _____

*The proctor should date and initial each category observed.

Area of Competence	Demonstrates Competence	Needs Supervision	Desires Training	Not trained or observed
Medical Records				
Interviewing/Hx taking				
Charting				
Informed Consent				
Client Education				
Referral/Follow-up system				
Productivity goals				
Lab Microscopy				
Venipuncture				
Wet Mounts/KOH/pH				
Dipstick				
Hematocrit				
Obtaining STD tests				
Exposure control procedures				
Other				
Procedures/Treatments # of procedures observed				
Vital signs				
IUC insertion (CU IUD/LNG IUS)	X			
Implanon insertion	X			
Implant removal				
Endometrial biopsy				
Ultrasound				
TCA/BCA application				
Vulvar Biopsy				
IM injection				
Diaphragm fitting				
FemCap fitting				
Emergency plans/drugs				
Skin Biopsy				
MVA	X			
Other				

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Area of Competence	Demonstrates Competence	Needs Supervision	Desires Training	Not trained or observed
Education				
Hormonal Contraceptives -General -Initiation -Problem Management				
Emergency contraception				
IUC	X			
Barrier Contraceptives				
Spermicide and Condoms				
Reproductive Life Planning				
Pregnancy Options				
Abortion -Medication -Surgical	X			
Other				
STDs/Vaginitis/UTI				
Bacterial Vaginosis				
Bartholinitis				
Candidiasis				
Cervicitis				
Chlamydia				
Gonorrhea				
HSV				
HIV counseling				
HPV				
Molluscum				
Pediculosis				
Syphilis				
Trichomonas				
UTI				
Other				
GYN Conditions				
Abnormal cytology/HPV follow up				
Abnormal Bleeding				
Amenorrhea				
Dysmenorrhea				
PID				
Galactorrhea				
Abnormal breast conditions				
Infertility				
Gestational Sizing				
HT/ET				
Other				

CLINICAL PRIVILEGING FORM

Colleen McNicholas has been granted clinical privileges for the following:

Date	Service	Signature of Medical Director or physician designee
4/15/15	☒ 1st trimester Surgical Abortion	
4/15/15	☒ Abortion pill	
4/15/15	☒ 2nd trimester Surgical abortion	
4/15/15	☒ Conscious Sedation	
	☐ Transabdominal Tubal Sterilization	
	☐ Hysteroscopic Tubal Sterilization	
	☐ Vasectomy	
	☐ Hysteroscopy	
	☐ LEEP	
	☐ Cryotherapy	
	☐ Colposcopy	
	☐ Endometrial Biopsy	
	☐ Vulvar Biopsy	
	☐ Fine Needle Aspiration	
	☐ Simple Cyst Aspiration	
4/15/15	☒ IUC insertion	
4/15/15	☒ Implanon insertion	
	☐ Implant removal	
4/15/15	☒ Standard U/S (Abortion)	
4/15/15	☒ Limited U/S (Abortion)	
	☐ Standard U/S (Pregnancy)	
4/15/15	☐ Limited U/S (Pregnancy)	
	☒ Limited U/S for IUC localization	
	☐ Standard U/S (GYN)	
	☐	
	☐	
	☐	

List any formal training clinician received for service(s) noted above:

Service	Year	Length of Training	Didactic component	Clinical Component
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no

I have read and understand the KM protocol. I agree to practice in accordance with this protocol when I am caring for clients at PPACM.

Clinician _____ Date 4/24/15

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Area of Competence	Demonstrates Competence	Needs Supervision	Desires Training	Not trained or observed
Cervical Screening				
Obtaining a Pap/HPV test				
Colposcopy				
Cryotherapy				
LEEP				
Abortion Services				
Surgical Abortion	X			
Medication Abortion	X			
Post-abortion check-up	X			
Recovery Room	X			
Management of complications	X			
High Alert Follow-up	X			
POC evaluation	X			
Other				
Referral Follow-up				

Proctor Signature: K Milburn Date: 4/24/15

RECOMMENDATION:

☒ Approved to provide services as checked in Column I above.

☐ Needs supervised clinical practice in the following areas:

Collum is currently practicing AB Services within an accredited affiliate

Plan for providing supervised clinical practice:

☐ Needs additional training in:

Plan for providing additional training (Journal review, In-service training, On-line training, CEU/Conference)

Signature of Clinician: [signature] Date: 4/24/15

Signature of MD or Physician Designee: [signature] Date: 5/04/2015

Print

Item Name	Status	Marked Complete By
Ultrasound in Abortion Care Advanced Placement (AP) Exam- Advanced **This advanced skills exam may be taken and passed to place out of courses 10-14 for Ultrasound in Abortion Care. Please note: In order to receive CME/ CE credit for the Ultrasound in Abortion Care Staff Training series, all 14 courses must be successfully completed.** Registration Date:04/01/2015	**Successful** On:04/01/2015 Score:85	
Ultrasound in Abortion Care Advanced Placement (AP) Exam- Basic **This basic skills exam may be taken and passed to place out of courses 1-9 of the Ultrasound in Abortion Care Series. Please note: In order to receive CME/ CE credit for the Ultrasound in Abortion Care Staff Training series, all 14 courses must be successfully completed.** Registration Date:03/31/2015	**Successful** On:04/01/2015 Score:95	

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PHYSICIAN PERFORMANCE REVIEW SUMMARY

Name of Physician: _____

The following section to be completed by the Vice President of Patient Services
Administrative Review

Based on professional communication, collaborative patient management, and/or individual patient care, the above physician performed satisfactorily in the following areas:

1.	Customer Orientation — understands, commits to and practices a market and customer oriented approach to heal care delivery. Treats clients with respect and non-judgmentally. Clients are satisfied after an encounter with this	1	2	3
2.	Initiative — seeks ways to make best use of time. Seeks professional development. Participates in proactive problems solving.	1	2	3
3.	Attendance and Productivity — arrives on time and stays until all patients are discharged. Shows up reliably on scheduled dates. Active participant in provider meetings.	1	2	3
4.	Relationship to Staff — treats support staff with courtesy and respect. Treats colleagues with respect. Is a "team player." Pleasant to work with.	1	2	3
5.	Assists with management of complex/complication management of patients?	Yes	No	NR
6.	Is readily available for consultation?	Yes	No	NR

1.	Credentialing	Satisfactory	Unsatisfactory	NR
2.	Complication Rates	Satisfactory	Unsatisfactory	NR
3.	Occurrence Report/Complaints	Satisfactory	Unsatisfactory	NR

Comments: Trustee to have her on provider team. Med. and patient focused. Advocate for care, public and in practice. Courageous. Protective. Team with training. Active in pt care, improvements. Has integrity, Wife of Marine

Manager's Signature _____ Date 10/21/14

Evaluation Summary
OVERALL JOB RATING
1 – Unacceptable 2 – Needs Improvement 3 – Satisfactory / Productive

Overall Rating: 3

Provider's Comments _____

Signatures

I certify by my signature below that this performance review has been discussed with me. I have read and understand the contents. I understand that my signature does not necessarily indicate agreement with statements made herein.

Physician Signature _____ Date 11/12/14

Medical or Program Director: _____ Date 11/12/14

Chief Executive Officer: _____ Date 11/13/14

CM is a leader among state + local (and national) MDs.
PMF

PHYSICIAN PERFORMANCE REVIEW SUMMARY

Name of Physician: Colleen McNicholas

Physician Annual Performance Review
RHS of PPSLR/SWMO

Definitions of terms used to evaluate work in the following sections:

1	Unacceptable – seldom meets established standards; must improve for continued employment.
2	Needs Improvement — sometimes meets established standard but lacks consistency; seldom exceeds and often falls short of desired results; must improve for continued employment.
3	Satisfactory/Productive — meets and /or exceeds established standards.

Clinical Review: Abortion Services

Date of review: 10/29/14

To be completed by Program Director or Medical Director

1.	Reviews history, lab and other finding. Refers out inappropriate patients	1	2	3
2.	Provides counseling and education as needed.	1	2	3
3.	Establishes effective rapport with staff and patients.	1	2	3
4.	Completes accurate physical assessment, especially in relation to uterine sizing.	1	2	3
5.	Utilizes correct abortion technique.	1	2	3
6.	Demonstrates appropriate use of correct procedures and personal protective equipment.	1	2	3
7.	Performs accurate assessment of POC.	1	2	3
8.	Understands and practices in accordance with RHS of PPSLR protocols.	1	2	3
9.	Accurately and thoroughly document all findings.	1	2	3
10.	Refers for further evaluation as indicated.	1	2	3
11.	Determines appropriate plan for follow-up.	1	2	3
12.	Complication Management.	1	2	3

Comments:

Physician Evaluator Signature [signature] Date 10/29/14

Goals (for next evaluation period)

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McNicholas

Reproductive Health Services of

Planned Parenthood of the St. Louis Region

Physician NextGen Review

- ✓ Log-in and 5 Point Check
- ✓ Reviewing Medical History
- ✓ 24 Hour Informed Consent
- ✓ EGA Documentation U/S vs LMP
- ✓ Reviewing STI Testing Results and other Labs
- ✓ Reviewing Medication Orders and Completion
- ✓ U/S Approval
- ✓ MedAB Documentation
- ✓ Additional Notes
  - o Time
  - o Content
  - o Name and Credentials

- ✓ IV Sedation Documentation
  - o Vitals and O2Sats through Sedation Grid
- ✓ Pelvic Exam and Uterine Orientation Documentation
- ✓ Surgical Template
  - o Type of Procedure
  - o Start/Stop Time
  - o Details of Procedure
  - o POC Exam
  - o Impression
  - o Plan
  - o Resident Name in Comments Section
  - o Desired BCM
  - o OK

- ✓ Complications
- ✓ Same Day Reaspiration

- ✓ Clinical Assessment of Viability starting at 14 weeks
- ✓ Intent Statements starting at 14 weeks
- ✓ Check Box for Intent starting at 14 weeks
- ✓ D&E Details starting at 14 weeks

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- ✓ IUC Insertion
  - Consents Signed
  - Type of Device with Exp Date and Lot Number
  - Appropriate Candidate
  - Side Effects Discussed
  - Pregnancy Terminated Today
  - Done Under U/S
  - Details of Insertion
  - Ryan Device?
  - OK only once

- ✓ Implant Insertion
  - Consents Signed
  - Type of Device with Exp Date and Lot Number
  - Appropriate Candidate
  - Side Effects Discussed
  - Pregnancy Terminated Today
  - Details of Insertion
  - Ryan Device?
  - OK only once

Date of Review: 12/6/13

Clinician: _____

Reviewer: _____

Americans United for Life

REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE SAINT LOUIS REGION
4251 FOREST PARK AVENUE •FIRST FLOOR• SAINT LOUIS MO 63108
(314) 531-7526

Reproductive Health Services
Planned Parenthood of the St. Louis Region

Physician / Clinician Name Colleen McNicholas

Performance & interpretation of ultrasound for pregnancy dating or surgical procedure assistance		X	X
Paracervical Block		X	X
Intravenous Sedation		X	X
Early Surgical Abortion (4 to 5 weeks)		X	X
First Trimester (5 weeks up to 13w6d) with Electric Vacuum Aspiration		X	X
First Trimester Uterine Manual Vacuum Aspiration		X	X
Medication Abortion (through 9 wks)		X	X
Laminaria/Dilapan insertion		X	X
2nd Trimester (≥ 14 weeks) One Day Procedures		X	X
Ultrasound guided feticidal injection		X	X
2nd Trimester Dilation and Evacuation with laminaria insertion (through 22 wks)		X	X
Postabortion IUC placement		X	X
Implanon placement		X	X
May provide 24 hour informed consent as a qualified professional and may supervise other qualified professionals who perform this duty under the direction of the Medical Director		X	

The above listed clinician is granted the above marked privileges

David L. Eisenberg, M.D., MPH
Program Director, Medical Director
Planned Parenthood of the St. Louis Region

7/1/13
Effective Date

RH\forms\drprivileges10/8/05/ 03/12/07/3/09; 7/10, 8/10

Physician Annual Performance Review
RHS of PPSLR/SWMO

Physician:	McNichols
Reviewed By:	Gaulke

Definitions of terms used to evaluate work in the following sections:

1	Unacceptable – seldom meets established standards; must improve for continued employment.
2	Needs Improvement — sometimes meets established standard but lacks consistency; seldom exceeds and often falls short of desired results; must improve for continued employment.
3	Satisfactory/Productive — meets and /or exceeds established standards.

Clinical Review: Abortion Services

To be completed by Program Director or Medical Director

1.	Reviews history, lab and other finding. Refers out inappropriate patients	1	2	3
2.	Provides counseling and education as needed.	1	2	3
3.	Establishes effective rapport with staff and patients.	1	2	3
4.	Completes accurate physical assessment, especially in relation to uterine sizing.	1	2	3
5.	Utilizes correct abortion technique.	1	2	3
6.	Demonstrates appropriate use of correct procedures and personal protective equipment.	1	2	3
7.	Performs accurate assessment of POC.	1	2	3
8.	Understands and practices in accordance with RHS of PPSLR protocols.	1	2	3
9.	Accurately and thoroughly document all findings.	1	2	3
10.	Refers for further evaluation as indicated.	1	2	3
11.	Determines appropriate plan for follow-up.	1	2	3
12.	Complication Management.	1	2	3

Comments:

Physician Evaluator Signature: [signature] Date 10-17-12

Goals (for next evaluation period)

The following section to be completed by the Vice President of Patient Services

Administrative Review

1.	Customer Orientation — understands, commits to and practices a market and customer oriented approach to heal care delivery. Treats clients with respect and non-judgmentally. Clients are satisfied after an encounter with this provider.	1	2	(3)
2.	Initiative — seeks ways to make best use of time. Seeks professional development. Participates in proactive problems solving.	1	2	(3)
3.	Attendance and Productivity — arrives on time and stays until all patients are discharged. Shows up reliably on scheduled dates. Active participant in provider meetings.	1	2	(3)
4.	Relationship to Staff — treats support staff with courtesy and respect. Treats colleagues with respect. Is a "team player." Pleasant to work with.	1	2	(3)

Based on professional communication, collaborative patient management, and/or individual patient care, the above physician performed satisfactorily in the following areas:

1.	Assists with management of complex/complication management of patients?	(Yes)	No	NR
2.	Is readily available for consultation?	(Yes)	No	NR

1.	Credentialing	(Satisfactory)	Unsatisfactory	NR
2.	Complication Rates	(Satisfactory)	Unsatisfactory	NR
3.	Occurrence Report/Complaints	(Satisfactory)	Unsatisfactory	NR

Comments: Allen has been a great addition to the surgical team. Per conversations with providers at ASC she has been a great help for our patients. Dr MN is fine clinician, increasing in her clinical skills, leadership. Asset to our team.

Manager's Signature: Mary Ann Legut VP of Patient Services Date: 10-17-12

Evaluation Summary

OVERALL JOB RATING

1 – Unacceptable 2 – Needs Improvement 3 – Satisfactory / Productive

Overall Rating: 3

Provider's Comments: _____

Signatures

I certify by my signature below that this performance review has been discussed with me. I have read and understand the contents. I understand that my signature does not necessarily indicate agreement with the comments made herein.

Physician Signature: _____
Date: 10/17/12

Medical or Program Director: _____
Date: 10/17/12

Chief Executive Officer: _____
Date: 10/18/12

Physician per review 7.09 / M

Americans United for Life

REPRODUCTIVE HEALTH SERVICES OF PLANNED PARENTHOOD OF THE SAINT LOUIS REGION
4251 FOREST PARK AVENUE ·FIRST FLOOR· SAINT LOUIS MO 63108
(314) 531-7526

Reproductive Health Services
Planned Parenthood of the St. Louis Region

Physician / Clinician Name Colleen McNicholas

Performance & interpretation of ultrasound for pregnancy dating or surgical procedure assistance		X
Paracervical Block		X
Intravenous Sedation		X
Early Surgical Abortion (4 to 5 weeks)		X
First Trimester (5 weeks up to 13wod) with Electric Vacuum Aspiration		X
First Trimester Uterine Manual Vacuum Aspiration		X
Medication Abortion (through 9 wks)		X
Laminaria/Dilapan insertion		X
2nd Trimester (≥ 14 weeks) One Day Procedures	X	
Ultrasound guided feticidal injection	X	
2nd Trimester Dilation and Evacuation with laminaria insertion (through 22 wks)	X	
Postabortion IUC placement		X
Implanon placement		X
May provide 24 hour informed consent as a qualified professional and may supervise other qualified professionals who perform this duty under the direction of the Medical Director		X

The above listed clinician is granted the above marked privileges

David L. Eisenberg, MD, MPH
Program Director, Medical Director
Planned Parenthood of the St. Louis Region

7/5/2011
Effective Date

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4401 W 109th St Ste 200
Overland Park, KS 66211
p: 913.312.5100 f: 913.312.3170
www.ppkm.org

Planned Parenthood of Kansas and Mid-Missouri

May 11, 2015

John Langston
Missouri Department of Health and Senior Services
Bureau of Ambulatory Care
PO Box 570
Jefferson City, MO 65102-0570

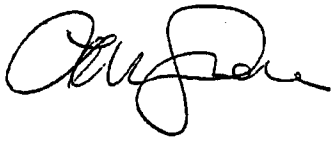
Re: Initial Licensure Survey

Dear Mr. Langston,

Planned Parenthood of Kansas & Mid-Missouri would like to request a waiver to the provision of 19 CSR 30-30.070 (2)(N) which requires that the recovery room shall be of sufficient size to accommodate at least 4 recovery beds or recliners for each procedure room. In order to meet the requirement of three feet of clear space on both sides and at the foot of each recovery bed or recliner, we request that we have 3 recovery recliners instead of 4.

We believe that 3 recovery chairs is sufficient for the planned licensed services and workload. This will in no way impact patient care.

Sincerely,



Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri (PPKM)
Planned Parenthood Advocates of Kansas and Mid-Missouri (PPAKM)

Americans United for Life

Langston, John

Subject: Columbia Licensure

From: Casey, Vicki [mailto:Vicki.Casey@ppkm.org]
Sent: Monday, June 01, 2015 8:44 AM
To: Langston, John
Subject: Columbia Licensure

Hello John,

Attached you will find the documents that were requested at our initial licensure survey. Included are:

1. Credentialing packet for Dr McNicholas:
   a. Appointment and approval by the Governing Body
   b. Dr McNicholas BNDD and DEA certificates
   c. Completed application
   d. Approval of privileges by Dr Moore
2. BNDD and DEA certificates for Columbia facility
3. Waiver/Variance request for recovery room chairs
4. FCSR checks for all staff - The Director of HR is aware that the FCSR must be run on all employees upon hire and has implemented a system to check all employees on a quarterly basis.

We are aware that we will only be approved for medical abortion procedures at this time. We understand that BAC will need to revisit the facility prior to our offering surgical procedures.

Please let me know if there is any other information you need.

Thank you,

Vicki Casey
Health Center Manager
Planned Parenthood of Kansas
& Mid Missouri
711 N Providence Rd
Columbia MO 65203
PH: 913-345-4671
FAX: 573-443-5671
vicki.casey@ppkm.org
PPKM works to ensure that every individual has the knowledge opportunity and freedom to make informed, private decisions about reproductive and sexual health.

[PPKM Logo: Care. No matter what.]<http://www.ppkm.org>

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

July 15, 2015

Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W 109th St, Ste 200
Overland Park, KS 66211

Dear Ms. McQuade:

In accordance with 19 CSR 30-30.070(1), the Missouri Department of Health and Senior Services (DHSS), Section for Health Standards and Licensure (HSL) has **approved** your request for a variance to **19 CSR 30-30.070(2)(N)** for Planned Parenthood of Kansas and Mid-Missouri, 711 N. Providence Road, Columbia, MO 65203, license number 16 ("PPKM"). The variance allows the recovery room to be of sufficient size to accommodate three recovery beds or recliners for its procedure room, rather than four or more, with three feet of clear space on both sides and at the foot of each recovery bed or recliner.

This variance for license number 16 will remain in effect until there is a change in procedure type performed at PPKM; other change in circumstances; or DHSS determines that there is a detrimental impact on the health, safety, or welfare of the patient, staff, or public.

PPKM must submit a copy of this variance letter with its annual licensure renewal. Should you have questions regarding this correspondence, please contact me at (573) 751-6154.

Sincerely,

William Koebel
Assistant Section Administrator
Section for Health Standards and Licensure

WK:sb

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

July 15, 2015

Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W 109th St, Ste 200
Overland Park, KS 66211

Dear Ms. McQuade:

In accordance with 19 CSR 30-30.070(1), the Missouri Department of Health and Senior Services (DHSS), Section for Health Standards and Licensure (HSL) has **approved** your request for a variance to **19 CSR 30-30.070(2)(N)** for Planned Parenthood of Kansas and Mid-Missouri, 711 N. Providence Road, Columbia, MO 65203, license number 16 ("PPKM"). The variance allows the recovery room to be of sufficient size to accommodate three recovery beds or recliners for its procedure room, rather than four or more, with three feet of clear space on both sides and at the foot of each recovery bed or recliner.

This variance for license number 16 will remain in effect until there is a change in procedure type performed at PPKM; other change in circumstances; or DHSS determines that there is a detrimental impact on the health, safety, or welfare of the patient, staff, or public.

PPKM must submit a copy of this variance letter with its annual licensure renewal. Should you have questions regarding this correspondence, please contact me at (573) 751-6154.

Sincerely,

William Koebel
Assistant Section Administrator
Section for Health Standards and Licensure

WK:sb

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Planned Parenthood of Kansas and Mid-Missouri

May 11, 2015

John Langston
Missouri Department of Health and Senior Services
Bureau of Ambulatory Care
PO Box 570
Jefferson City, MO 65102-0570

Re: Initial Licensure Survey

Dear Mr. Langston,

Planned Parenthood of Kansas & Mid-Missouri would like to request a waiver to the provision of 19 CSR 30-30.070 (2)(N) which requires that the recovery room shall be of sufficient size to accommodate at least 4 recovery beds or recliners for each procedure room. In order to meet the requirement of three feet of clear space on both sides and at the foot of each recovery bed or recliner, we request that we have 3 recovery recliners instead of 4.

We believe that 3 recovery chairs is sufficient for the planned licensed services and workload. This will in no way impact patient care.

Sincerely,

Laura McQuade
President & Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri (PPKM)
Planned Parenthood Advocates of Kansas and Mid-Missouri (PPAKM)

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

September 25, 2015

Laura McQuade
President and Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W. 109th St., Ste. 200
Overland Park, KS 66211

Re: abortion facility license no. 16-2 (Columbia, Missouri facility)

Dear Ms. McQuade:

State licensure regulations require that physicians performing abortions at abortion facilities must have staff privileges at a hospital within fifteen minutes travel time from the facility. Based on recent action by MU Health Care, effective December 1, 2015, the physician performing abortions at the Columbia facility will no longer have the required privileges. As a result, as of December 1, 2015, the Columbia facility will not be in compliance with state licensure mandates.

Unless the facility satisfies this hospital privileges requirement, the license of the Columbia facility will be revoked on December 1, 2015.

If you have any questions, please contact me at (573) 751-6083.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

November 25, 2015

Via certified mail, no. 7007-0710-0002-2054-4232
Via email to Laura.McQuade@ppkm.org

Laura McQuade
President and Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W. 109th St., Ste. 200
Overland Park, KS 66211

Re: Revocation of abortion facility license no. 16-2 (Columbia, Missouri facility)

Dear Ms. McQuade:

On September 25, 2015, the department notified you that the above abortion facility license would be revoked on December 1, 2015, based on MU Health Care's discontinuance of the facility's physician's privileges.

As stated in the September 25, 2015 notice, state licensure regulations require that physicians performing abortions at abortion facilities have staff privileges at a hospital within fifteen minutes travel time from the facility. Based on MU Health Care's action, effective December 1, 2015, the physician performing abortions at the Columbia facility will no longer have the required privileges. As a result, as of December 1, 2015, the Columbia facility will not be in compliance with state licensure mandates.[1]

To date, the department has not been notified of the facility's ability to satisfy the physician privileges requirement on and after December 1, 2015. Therefore, under Section 197.220, RSMo, the department hereby revokes abortion facility license no. 16-2, effective at the facility's close of business on November 30, 2015.

Pursuant to Section 197.221, RSMo, the facility may file a complaint with the Missouri Administrative Hearing Commission, P.O. Box 1557, Jefferson City, Missouri 65102, within thirty days after the delivery or mailing by certified mail of this decision.

If you have new and pertinent information regarding the facility's ability to satisfy the physician privileges requirement, please let me know as soon as possible.

If you have any questions, please call me at (573) 751-6083.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

[1] *See* 19 CSR 30-30.060(1)(C)4 (physicians performing abortions at abortion facilities must have staff privileges at a hospital within fifteen minutes travel time from the facility); 19 CSR 30-30.060(1)(B)12 (administrator of abortion facility must ensure adherence to Chapter 188, RSMo); and Section 188.080, RSMo (physician performing or inducing abortion who does not have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced shall be guilty of a class A misdemeanor).

Missouri Department of Health and Senior Services
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Peter Lyskowski
Acting Director

Jeremiah W. (Jay) Nixon
Governor

June 23, 2016

Via certified mail, no. 7014-1820-0000-3523-5021
Via email to Laura.McQuade@ppkm.org and Vicki.Casey@ppkm.org

7014 1820 0000 3523 5021

Laura McQuade
President and Chief Executive Officer
Planned Parenthood of Kansas and Mid-Missouri
4401 W. 109th St., Ste. 200
Overland Park, KS 66211

Re: application for licensure of Columbia, Missouri abortion facility

Dear Ms. McQuade:

The department received the application for licensure of the Columbia, Missouri abortion facility located at 711 North Providence Road. The current license for the facility expires on June 30, 2016. As soon as possible, please let me know whether the facility will have a physician with the required privileges[1] by July 1, 2016. If the facility will have such a physician by then, as soon as possible, please provide me with written documentation evidencing the privileges. The department will then work with the facility to schedule an inspection.

The department will not grant the facility a license until the facility has a physician with the required privileges and the department has conducted an inspection to confirm that licensure requirements are met.

If you have any questions, please call me at (573) 751-6083.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

[1]*See* 19 CSR 30-30.060(1)(C)4 (physicians performing abortions at abortion facilities must have staff privileges at a hospital within fifteen minutes travel time from the facility); 19 CSR 30-30.060(1)(B)12 (administrator of abortion facility must ensure adherence to Chapter 188, RSMo); and Section 188.080, RSMo (physician performing or inducing abortion who does not have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced shall be guilty of a class A misdemeanor).

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Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 2, 2016

Vicki Casey (vicki.casey@ppgreatplains.org)
Comprehensive Health of Planned Parenthood Great Plains
711 North Providence Road
Columbia, Mo 65203

Re: Comprehensive Health of Planned Parenthood Great Plains – Columbia Survey

Dear Ms. Casey:

The Department received the application for licensure of the Columbia Planned Parenthood location as an abortion facility. Department staff conducted an onsite survey of the location on October 11, 2016 to determine compliance with the terms of the 2010 settlement agreement and applicable statutes and regulations, including the Ambulatory Surgical Center Licensing Law (Section 197.200, RSMo, et seq.) and Chapter 188, RSMo (Regulation of Abortions).

Listed below are items the survey indicated were not in compliance. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued.

19 CSR 30-30.060(1)(B) 12. The administrator shall be responsible for ensuring that the provisions of Chapter 188 RSMo, Regulation of Abortions, are adhered to.

- Sections 188.027 and 188.080, RSMo, require that all physicians performing or inducing abortions have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced. Neither of the facility's two physicians had the required privileges.
- Section 188.047 requires that tissue removed at the time of the abortion be submitted to a pathologist for necessary reporting. The facility did not have a finalized agreement with a pathologist to provide the required services.

19 CSR 30-30.060(1)(C)4. Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility.

- The facility did not have a documented working arrangement with a hospital within the required proximity.
- Neither of the facility's two physicians had the required privileges.

19 CSR 30-30.060(1)(C)1. The medical staff shall develop and, with the approval of the governing body, shall adopt policies governing physician activities in the abortion facility. Medical staff membership shall be limited to physicians.

- The facility policy failed to limit medical staff membership to physicians. The policy stated that advance practice registered nurses could be a member of the medical staff.

19 CSR 30-30.060(1)(C)3. The governing body, acting upon recommendations of the medical staff, shall approve or disapprove appointments. Written criteria shall be developed for privileges extended to each member of the staff. A formal mechanism shall be established for recommending to the governing body delineation of privileges, curtailment, suspension or revocation of privileges and appointments and reappointments to the medical staff.

- The facility had two physicians on staff. Not all components of a fully credentialed file had been completed for the physicians, including a formal approval of internal facility privileges, appointment to the medical staff, a National Practitioner's Data Bank check, or certifications from BNDD or DEA.

19 CSR 30-30.060(1)(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.

- The facility failed to demonstrate compliance with facility's established Infection Prevention Program, based on Association for the Advancement of Medical Instrumentation standards.
    - The facility did not maintain an autoclave log with the required components tracked (lot number, specific contents of the lot or load, exposure time and temperature, name and initials of the operator, results of biological testing).
    - The facility failed to have the supplies necessary for high level disinfection of vaginal ultrasound probes.

19 CSR 30-30.060(3)(J). Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body.

- The facility did not have a quality assurance program specific to their facility that included the required elements. Facility staff indicated a system-wide QAPI program that had removed elements required by Missouri rules some time before:
    - Intraoperative and postoperative complications
    - All cases that resulted in a length of stay of more than twelve (12) hours, and
    - All cases in which the gestational age was determined to be beyond eighteen (18) weeks.

19 CSR 30-30.060(3)(K). The quality assurance program must show evidence of action taken as a result of the identification of the problems.

- The facility program did not show identification of problems or follow-up of problems.

19 CSR 30-30.060(4)(C). All tissue obtained from abortions, except tissue submitted to a pathologist for analysis, shall be submerged in a preservative solution and shall be transported in a leakproof container to a facility with a waste sterilizer or an incinerator approved by the Department of Natural Resources. If kept for more than twelve (12) hours, all tissue shall be refrigerated.

- The facility failed to produce a final agreement with a pathologist.
- The facility did not have a preservative solution onsite.
- The facility did not have an agreement, approved by the Department of Natural Resources, with a waste sterilizer.
- The facility could not demonstrate whether adequate refrigeration space was available for preservation.

19 CSR 30-30.060(4)(E). Anti-Rh immune globulin therapy shall be given to all Rh negative patients upon completion of the abortion procedure.

- The facility failed to stock the required anti-Rh immune globulin.

19 CSR 30-30.060(3)(I). An emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest and cardiac arrest shall be immediately available to the procedure room and recovery room.

- The facility had two lists of supplies, one for medical and one for surgical abortion procedures. Some necessary medications and supplies were not onsite or had not yet been ordered for either type of procedure (including filter needles, one milliliter syringes, and cervical needles from the surgical supply list).

19 CSR 30-30.070(2)(N). The recovery room . . . shall be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner.

- Required space within the recovery room is not sufficient for at least four (4) recliners with three feet of clear space on both sides and at the foot of each recovery recliner. When this location was previously licensed in 2015, the facility had requested and been granted a variance for three (3) recliners. However, at that time the facility was only approved to provide medication procedures. It is now the facility's intent to also perform surgical procedures. The letter from the department dated July 15, 2015 states that the variance "will remain in effect until there is a change in procedure type performed at [the facility.]" The facility may submit a revised variance request in writing in accordance with 19 CSR 30-30.070(1).

19 CSR 30-30.070(2)(X). A patient toilet with lavatory shall be located convenient to the recovery room. This room shall be equipped with a constant running exhaust.

- The toilet room next to the recovery room has an exhaust fan which runs only when the light to the room is turned on and is activated by the same switch. A constant running exhaust in the patient toilet facility is specifically required in the 2010 settlement agreement (page 17).

Please respond in writing providing evidence/documentation that each of these items has been fully addressed and corrected.

If you have further questions, you may contact our office at 573-751-6083 or via email at the address noted below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

LAW OFFICES
ARTHUR BENSON & ASSOCIATES

ARTHUR BENSON
JAMIE KATHRYN LANSFORD

4006 CENTRAL STREET
KANSAS CITY, MISSOURI 64111-2236
816-531-6565 • 816-531-6688 FAX

EMAIL: abenson@bensonlaw.com
jlansford@bensonlaw.com
WEBSITE www.bensonlaw.com

November 11, 2016

VIA EMAIL: John.Langston@health.mo.gov

John Langston
Administrator, Bureau of Ambulatory Care
Missouri Department of Health and Senior Services
912 Wildwood
PO Box 570
Jefferson City, MO 65102-0570

Dear Mr. Langston:

Comprehensive Health of Planned Parenthood Great Plains ("Planned Parenthood") is in receipt of your letters dated November 2, 2016 regarding DHSS's surveys of Planned Parenthood's Columbia and Kansas City health centers, and we write to provide an initial response to those letters.

First and foremost, we are very disappointed to learn that DHSS intends to enforce Missouri's clearly unconstitutional requirements that facilities that provide abortion be licensed as ambulatory surgical centers and that physicians who provide abortions have local hospital admitting privileges. As we have indicated in previous correspondence to the Department, the United States Supreme Court has made clear in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), *as revised* (June 27, 2016), that these requirements, which do not promote women's health, impose an undue burden on women's access to abortion.

Moreover, while we will provide detailed responses to your letters in due course, we wanted to promptly note a few items for your reconsideration. In particular, with regard to the status of the admitting privileges of the physician at the Brous health center in Kansas City, we have learned that due to a clerical error, those privileges were changed by Menorah Medical Center in 2015 to non-surgical privileges. The hospital has indicated that the physician will need to go through a reappointment process to return his privileges to a clinical/surgical level. That process is underway. However, as you know, this physician does have surgical privileges at Overland Park Regional Medical Center which, while not specifically listed in the 2010 settlement agreement, is the same distance from the Brous health center as Menorah Medical Center and provides similar services. Given the similarity between the two hospitals, any conceivable patient health and safety benefit from having surgical privileges at Menorah Medical Center would be equally met by this physician's existing privileges – especially given that the Brous health center seeks to provide only medication abortion, a non-surgical service.

With regard to the Columbia health center, since the survey was completed Planned Parenthood has secured a written transfer agreement with a hospital within 15 minutes' travel time of this health center. This fulfills the requirement of 19 CSR 30-30.060(1)(C)(4). A number of the remaining items you identified with respect to the Columbia facility seem far from a basis on which to deny licensing. For example, we find it inexplicable that DHSS is deeming the Columbia health center's current waiver regarding the number of recliners in the recovery room insufficient and is requiring a new waiver application, and that DHSS is finding the facility's bathroom fan insufficient, as both these current conditions were approved by DHSS for purposes of the facility's license that recently expired in June 2016 -- and, indeed, have been approved consistently since the settlement agreement was entered, for the provision of both medication and surgical abortion. In addition, several of the items included in the letter regarding the Columbia health center required only minor policy adjustments, which, as you know, were already completed by the time the Brous health center survey occurred (and, presumably, is why those items were not listed in the letter regarding Brous). The remaining items in your letter require only minor administrative adjustments and the stocking of basic supplies necessary for the provision of abortion services, which, as an experienced abortion provider, Planned Parenthood is of course prepared to have in place.

However, it seems that trying to remedy these minor issues would be a waste of Planned Parenthood's resources as long as DHSS continues to enforce the physician privileges requirement. Therefore, please advise us within the next 7 days whether the information provided above regarding Planned Parenthood's physicians' privileges and the Columbia health center's transfer agreement changes DHSS's position about physician privileges.

Thank you for your consideration.

Sincerely,

Arthur Benson

Arthur Benson

Melissa Cohen
Planned Parenthood Federation of America
123 William Street
New York, NY 10038
(212) 261-4649

cc via email:

Nikki Loethen
General Counsel
Missouri Department of Health and Senior Services
Nikki.loethen@health.mo.gov

cc via U.S. Mail:

Chris Koster
Missouri Attorney General
Missouri Attorney General's Office
Supreme Court Building
207 W. High St.
P.O. Box 899
Jefferson City, MO 65102

Daniel Knight
Boone County Prosecuting Attorney
705 E. Walnut St
Columbia, MO 65201-4485

Jean Peters Baker
Jackson County Prosecutor
Jackson County Courthouse
415 E 12th Street
Kansas City, MO 64106

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Peter Lyskowski
Director

Jeremiah W. (Jay) Nixon
Governor

November 18, 2016

Via email to abenson@bensonlaw.com

Arthur Benson
Arthur Benson & Associates
4006 Central Street
Kansas City, Missouri 64111-2236

Re: Comprehensive Health of Planned Parenthood Great Plains – Kansas City and Columbia facilities

Dear Mr. Benson:

This is in response to your November 11, 2016, letter to me regarding physician privileges at the Kansas City and Columbia, Missouri Planned Parenthood facilities.

Regarding physician privileges at the Kansas City facility, the 2010 settlement agreement states (page 19), "PPKM represents that medication abortion at the Brous Center is provided by a physician licensed to practice in Missouri who has privileges to perform surgery either at Menorah Medical Center or Research Medical Center. This will fulfill the physical presence requirements of 19 CSR 30-30.060(3) and (3)(A) and (3)(D) and the staff privileges requirement of 19 CSR 30-30.060(1)(C)4."

Your letter states that the Kansas City facility has a physician with surgical privileges at Overland Park Regional Medical Center who would provide medication abortions. Such privileges do not comply with the settlement agreement. Until the facility is in compliance with the privileges requirement of the settlement agreement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Regarding the Columbia facility, your letter states that the facility "has secured a written transfer agreement with a hospital within 15 minutes' travel time" from the facility "which fulfills 19 CSR 30-30.060(1)(C)(4)."[1] The department has not received a copy of this agreement and is therefore unable to confirm whether it complies with the regulation. Regardless, the facility still must comply with 19 CSR 30-30.060(1)(B)12, which states, "The administrator shall be responsible for ensuring that the provisions of Chapter 188 RSMo, Regulation of Abortions, are adhered to." Sections 188.027 and 188.030, RSMo,

[1] Regulation 19 CSR 30-30.060(1)(C)4 states, "Physicians performing abortions at the facility shall have staff privileges at a hospital within fifteen (15) minutes' travel time from the facility or the facility shall show proof there is a working arrangement between the facility and a hospital within fifteen (15) minutes' travel time from the facility."

require that all physicians performing or inducing abortions have clinical privileges at a hospital which offers obstetrical or gynecological care located within thirty miles of the location at which the abortion is performed or induced. Neither of the facility's two physicians have the required privileges. Until the facility is in compliance with the privileges requirement, an abortion facility license cannot be granted, even if all other deficiencies identified in the department's November 2, 2016, letter were corrected.

Additionally, page two of your letter states, "A number of the remaining items you identified with respect to the Columbia facility seem far from a basis on which to deny licensing." To be clear, the department has not denied licensure; the department has identified the deficiencies that must be corrected before licensure could be granted.

If you have additional questions, you may contact our office at (573) 751-6083 or via email at the address below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Planned Parenthood®
Care. No matter what.

Comprehensive Health
4401 W. 109th St Suite 100
Overland Park, KS 66211
p: 913.345.1400 f: 913.345.2820
www.PPGreatPlains.org

Comprehensive Health of
Planned Parenthood Great Plains

June 5, 2017

John Langston
Bureau of Ambulatory Care
MO Department of Health & Senior Services
POB 570
Jefferson City MO 65102

Dear Mr Langston:

Enclosed are our responses to your request for additional clarification regarding the items that were cited at the October 2016 license survey at the Columbia and Patty Brous locations.

Please let me know if you need anything further.

Sincerely,

Amanda Addison
Vice President of Health Services
Planned Parenthood Great Plains
amanda.addison@ppgreatplains.org
PH: 913-345-4659

Received
6/7/17

19 CSR 30-30.060(1)(C)1. The medical staff shall develop and, with the approval of the governing body, shall adopt policies governing physician activities in the abortion facility. Medical staff membership shall be limited to physicians.

- The facility policy failed to limit medical staff membership to physicians. The policy stated that advance practice registered nurses could be a member of the medical staff. **Clarification/question: In the medical staff bylaws, allied health staff are mentioned. The bylaws say only physicians are on medical staff at first, but allied health (page 2 of 9 bylaws) are still referred to as needing a credentialing packet. Can you clarify if that means these individuals are credentialed to be on medical staff or this is just another way to denote the application for some degree of clinical privileges?**

The medical staff bylaws (page 2) refer to the need for clinicians to be credentialed with ARMS who is our liability insurance provider. Please see second bullet point from the bottom of page 2 stating that a certificate of insurance will be provided once the process is complete. This process is called "professional credentialing".
Please see Exhibit 1.

Related Clarification/question: Having privileges approved for the physicians was mentioned in our letter and you mention physicians were approved in your response. However, you didn't list specific privileges or what was approved. [Note, this is specific to privileges granted at your facility, not hospital privileges which was specifically covered by the federal court order.]
Please see Exhibit 2 for Clinical Privileging forms.

19 CSR 30-30.060(1)(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.
The facility failed to have the supplies necessary for high level disinfection of vaginal ultrasound probes. **Clarification/question: The procedure for high level disinfection (HDL) contains a back-up procedure that consists of soaking vaginal probes in a bleach solution. Bleach is not an FDA-approved HLD. For reference see:**https://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm
PPGP removed the use of bleach as a back-up high level disinfectant in the Cleaning the Ultrasound Probe and Care of the Ultrasound Machine Policy. All health centers performing ultrasounds will keep an adequate amount of Resert in stock, so that no back-up is needed. Please see Exhibit 3 for updated policy.

19 CSR 30-30.060(4)(C). All tissue obtained from abortions, except tissue submitted to a pathologist for analysis, shall be submerged in a preservative solution and shall be transported in a leakproof container to a facility with a waste sterilizer or an incinerator approved by the Department of Natural Resources. If kept for more than twelve (12) hours, all tissue shall be refrigerated.

Clarification/question: Your original response states that all tissues (100% of POC) are sent to pathologist so there is no need for the facility to have an agreement with a waste sterilizer. However, there is no information from the pathologist contract anything regarding disposition of tissues. We would like further information in writing on the disposition of tissue by the pathologist to ensure that disposition is by appropriate means and methods. This is part of the abortion provider's overall responsibility to ensure all applicable portions of Chapter 188 is met per CSR 30-30.060(1)(B)(12)

PPGP has conferred with Boyce and Bynum and have been informed that all pathology specimens from abortion are incinerated in accordance with all Missouri laws and regulations. Boyce and Bynum uses an approved waste hauler and an approved incinerator.

Related Clarification/question: On the facility's agreement with the pathology group, it doesn't specifically state that the pathologist will do the state reporting required by chapter 188.047 (Although it does have an overall statement they will comply with state law.) Please clarify in writing that the agreement with the pathology group include all required reporting as required by 188.047 (providing a copy of the pathology report to both the abortion facility as well as the DHSS)

PPGP has confirmed with Boyce and Bynum that they will provide a copy of the pathology report to both the abortion facility and the Department of Vital Statistics within 30 days of the examination of the tissue, as required.

Americans United for Life

Exhibit 1

Licensed Independent Providers Policies & Procedures

Medical Staff

The Medical Staff is a formal organization of physicians who are appointed by the Board of Directors to provide patient care at Comprehensive Health of Planned Parenthood ambulatory surgery centers. The Medical Staff and Board of Directors collaborate to enhance the quality and safety of care, treatment, and services provided to patients. As an ambulatory surgery center licensed by the Kansas Department of Health and Environment in Kansas and Department of Health and Senior Services in Missouri (19 CSR 30-30.060), CHPPGP is required to have a Medical Staff of one or more physicians in Kansas (Kansas Ambulatory Surgery Center Regulations 28-34-50(b)(1) and three or more physicians in Missouri.

Medical Staff Membership

All physicians who work at CHPPGP are Medical Staff members. At PPGP/CHPPGP, the credentialing application is also the application for CHPPGP Medical Staff membership.

Medical Staff Bylaws for the CHPPGP ASC Medical Staff are located in the PPFA Medical Director Orientation Manual (2014) and Clinician Performance Monitoring Toolkit (2013).

CHPPGP Medical Staff Meetings occur quarterly immediately following the All-Staff meeting and are led by the Medical Director with administrative assistance to draft the agenda, send meeting invitations, record attendance and draft the minutes. The minutes are approved by the Medical Director. The CHPPGP Medical Staff members may invite other licensed independent providers (LIP), including advance practice registered nurses and physician assistants, to attend the Medical Staff meeting.

Medical Director

The Medical Director supervises all aspects of medical care at PPGP/CHPPGP. The Medical Director's responsibilities include performing or delegating the following:

- Leads the CHPPGP Medical Staff
- Oversees family planning, abortion and colposcopy programs
- Implements and updates the Medical Standards and Guidelines (MS&Gs)
- Develops or approves medical and clinical policies & procedures
- Ensures provider orientation, education, privileging, periodic chart review, and annual Ongoing Professional Practice Evaluation (OPPE) occur
- Establishes relationships within the medical community and participates in formulation of the referral list
- Serves as Laboratory Director
- Leads the Quality/ Peer Review Committee
- Reviews significant medical incidents in STARS and makes recommendations
- Assists legal counsel in responding to State regulatory investigations

- Serves as the collaborative practice agreement physician in Kansas and Missouri
- Serves as the Ultrasound Director to ensure staff and physician training and competence
- Serves on the PPGP/CHPPGP Quality/Risk Management Steering Committee

Professional Credentialing Policy

PPGP/CHPPGP demonstrates its commitment to being a health care leader that provides a consistently high level of quality care to the community by ensuring that all professional staff possess the appropriate licensure, education and relevant training. PPGP/CHPPGP requires its licensed independent providers (LIPs), at a minimum, to possess the credentials delineated in the ARMS Clinical Performance Monitoring Toolkit (2013).

The Director of CQRM uses the PPFA/ARMs credentialing service to verify the credentials of all physicians, Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Registered Nurses (RNs) and Licensed Social Workers (LSWs). Verification is sought to confirm that the provider has the education, training, skill sets, judgment, character, integrity, ability to work with others, and practice patterns to provide patient care at PPGP/CHPPGP. Credentialing occurs at the time of hire. Re-credentialing occurs every 3 years thereafter. This process is called "professional" credentialing to distinguish it from the process of "insurance" credentialing, performed by the finance and billing department.

Credentialing Procedure

The Director of CQRM will:

- Coordinate with Human Resources so that new providers are given the credentialing application immediately at the time of hire because it takes from 15 to 30 days to verify credentials. The process must start immediately in order to be completed before orientation ends. A new LIP should not care for patients independently until credentials are verified or insurance carriers may not pay for the care.
- All new physicians, APRNs, PAs, RNs and LSWs must complete the credentialing application and return it with a curriculum vitae and their DEA number, if relevant, within 5 days of hire. All gaps in employment must be explained. ARMS requires the professional credentialing process to have begin within 10 days of hire in order for the provider to see patients. If the provider cannot work because he/she did not return the application on time, PPGP/CHPPGP may not pay the provider until the application is submitted.
- Upload the application and CV to the credentialing service.
- Complete the ARMS request for a certificate of insurance (COI) naming the provider.
- Purchase special professional liability insurance for Certified Nurse Midwives (CNMs) and physician assistants who practice in Kansas. The most affordable option has been to buy insurance through our agent with KaMMCO. CNMs and

physician assistants must have special insurance because Kansas makes them pay into the Kansas Health Care Stabilization Fund.

- Notify the insurance credentialer that the provider is onboarding and fill out the shared provider spreadsheet with NPI number, DEA number, date of birth, etc. The spreadsheet is here: Q drive > Credentialing folder. The insurance credentialer will enter the LIP into the CAQH database and credential the LIP with third party payers.
- Query the National Provider Data Bank (NPDB) and download the provider's report.
- Draft collaborative practice agreements (CPA) for APRNs in Kansas, Missouri and Arkansas. Best practice is for the APRN to sign contracts with both the collaborating physician and a backup collaborating physician.
- Remind APRNs who will be prescribing testosterone in Missouri to submit an application for Controlled Substance Prescriptive Authority and a Notice of Delegated Prescriptive Authority for Controlled Substances with the Missouri State Board of Nursing. Send the CPA physician 10% of charts and 20% of controlled substance prescriptions every 2 weeks for review if required by State law.
- Download the verified credential report when it is ready.
- Review report for adverse events and, if necessary, request additional information to understand them.
- Give the practitioner's report to Human Resources to put into the provider's file.
- Give the RN or LSW's report to the VP Clinical Services.
- If the new physician works in the Kansas ASC or a Missouri abortion facility, remind the Board of Directors to approve the Medical Staff appointment as required by Kansas and Missouri regulations.
- Note: The new clinician orientation process and checklist are located in the Operations Manual section on Staff Standards.

Re-Credentialing Process

ARMS requires all physicians, APRNs, PAs. RNs, and LSWs to re-credential every 3 years. The Director of CQRM will:

- Annually, request the ARMS credentialing service to provide a spreadsheet of all credentialed staff and note which ones are due for the 3-year re-credentialing.
- Ask these staff to complete the re-credentialing application and return it.
- Upload the completed application to the credentialing service.
- Check the practitioner's name in the NPDB.

Credential Maintenance Policy

It is the policy of PPGP/CHPPGP that each professional has the responsibility to renew her/his own licenses and certifications, that licensed staff do not provide patient care if a mandatory license or certification lapses, and that professionals who allow a license or certification to lapse are subject to disciplinary action. If a LIP provides patient care after their certification or license lapses, and the insurance company (including

Medicaid) denies the claim due to the lapse, the LIP may be asked to reimburse PPGP/CHPPGP for denied claim.

Credential Maintenance Procedure

PPGP/CHPPGP has a process to ensure that its health care providers maintain required licensure and certification.

- As a courtesy, professionals may be reminded to renew licenses and certifications 60 and 30 days before expiration. PPGP/CHPPGP assumes no responsibility if a license or certification expires.
- In Missouri, APRNs must:
  - fax their renewed certification to the Missouri State Board of Nursing
    - The fax number is: **573-522-2143**
  - save the fax confirmation receipt.
  - After sending the fax, APRNs will telephone the Missouri State Board of Nursing to confirm the Board received their certification renewal.
    - The phone number to call is: **573.751.0681**
  - The APRN will document this phone call and save the documentation because the Missouri State Board of Nursing has denied receiving several faxed certifications in 2015 and 2016.
- The Director of CQRM will search on line to make sure the appropriate licensing entity posted the renewal.
- The Director of CQRM will notify the VP of Health Clinical Services and the Revenue Cycle Director if a license or certification expires (Medicaid may not reimburse care provided by an LIP with expired credentials).

Privileging Policy

It is the policy of PPGP/CHPPGP that only those health professionals who by state law, education and training are qualified to perform a particular clinical function are allowed to do so. Specialized services must only be provided by clinicians who are trained and demonstrate proficiency in those specific areas. Examples include, but are not limited to, performing ultrasound, colposcopy and Norplant and IUC insertions and removals. Determining the competency of each clinician is the responsibility of the Medical Director for physicians or Lead Clinician for APRNs and PAs.

Privileging Process

Newly Hired Practitioner – all newly hired physicians and APRN/PAs must undergo a period of supervised practice called proctoring. Proctoring is required regardless of pay status (employed, contracted, volunteer), length of experience prior to joining, or length of service (ex. employed 5 years and begins providing colposcopies). Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and is delegated to the Lead Clinician for PA/APRNs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form located in the PPFA Clinician Performance Monitoring Toolkit.

Practitioners Seeking Additional Privileges will be proctored by a practitioner who is privileged to perform the procedure. Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and Lead Clinician for APRN/PAs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form, located in the PPFA Clinician Performance Monitoring Toolkit.

Ongoing Professional Practice Evaluation Policy

It is PPGP/CHPPGP's policy to conduct ongoing professional practice evaluation (OPPE) at least annually to ensure clinicians are providing and documenting care consistent with the MS&Gs and the PPGP/CHPPGP mission. If OPPE reveals adverse data, the Medical Director will develop a performance improvement plan that may include altering the provider's privileges, additional proctoring, education, discipline, or termination, in order to ensure patient safety.

Ongoing Professional Practice Evaluation Procedure

PA/APRN OPPE

The Medical Director is responsible for APRN/PA OPPE but may delegate the review to the Lead Clinician. The Lead Clinician will report all findings to the Medical Director for final determination of competency. Competency will be evaluated within 3 months of hire and annually at a minimum.

Methods of review include:

- Chart Audit: The Lead Clinician will audit at least 10 patient charts for the PA/APRN annually and as needed.
- Observation: The Lead Clinician will observe the APRN/PA during orientation and annually. Areas of observation will include history taking, patient education, physical assessment, infection control, patient management, and charting.
- Microscopy: The Lead Clinician will assess Vaginal Wet Mount Microscopy accuracy semi-annually and will evaluate competency annually. At the annual evaluation, microscopy skills will be observed. In addition, at least 5 slides will be reviewed by the APRN/PA and the Lead Clinician with an expectation of 80% agreement. Semi-annually, the APRN/PA will be tested on reading at least 4 microscope photos with an expectation of 100% accuracy.
- Training and Meetings: PA/APRNs are expected to participate in PPGP/CHPPGP Leadership Team Meetings and training opportunities.
- Referral Protocol: The Lead Clinician will review APRN/PA compliance with the referral protocol via annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.
- Pap Protocol: PA/APRNs will be reviewed for compliance with the abnormal pap protocol. Review will be by annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.

Lead Clinician OPPE

The Medical Director will perform the Lead Clinician's OPPE based on the above review methods. Additionally, the Lead Clinician will be evaluated on her/his oversight of the provision of clinic medical services, including APRN/PAs, medical assistants, RNs, LPNs, and student PA/APRNs. The Lead Clinician will be evaluated on how well she/he works with the clinic managers to communicate any changes in medical care and protocols to clinic staff.

Physician OPPE

The Medical Director is responsible for performing physician OPPE. Competency will be evaluated within 3 months of hire and annually. The Medical Director will employ the following methods of review:

- Observation: Areas of review will include surgical technique, communication with staff, professional rapport with patients and infection control.
- Chart Audit: Patient care chart audits of at least 10 charts will be performed annually and as needed to assure compliance with the MS&Gs. All areas of service the physician provides will be included. Areas of review will include consent, history, lab, assessment, plan, and referral.
- Risk Management: Physician complication statistics will be compiled annually and reviewed for trends by the Medical Director, staff physicians, Director of CHPPGP, and Director of Quality and Risk Management. An annual complication rate will be included in the annual physician review with an expectation of less than 2% complication rate.
- Training and Meetings: Physician is expected to participate in CME meetings and training opportunities.

Medical Director OPPE

The Medical Director's OPPE will be performed by an outside physician consultant. Additionally, the Medical Director will be evaluated on how well he/she fulfills the Medical Director job description.

Ultrasound Quality Improvement Program OPPE

PPGP has an ongoing ultrasound quality improvement program for all staff that performs ultrasounds that includes:

- Initial training
- Proctoring
- Privileging
- Monitoring
- Ongoing proficiency

All staff who perform ultrasounds for abortion care will demonstrate competence initially by completing the Ultrasound Privileging form (located in the PPFP Clinician Performance Monitoring Toolkit (2013), watching the CAL ultrasound videos, proctering an annual observation and annual chart review of 10 random chart by the Lead Clinician.

Quality/Peer Review Policy

Where OPPE occurs annually and examine the provider's competence, the Quality / Peer Review Committee (QPRC) meets quarterly and examines unwanted clinical outcomes for trends and opportunities for improvement. It is the policy of PPGP/CHPPGP for the QPRC to review all unwanted patient outcomes. The process is protected under state and federal physician peer review, quality improvement, and patient safety statutes. Each participant should sign a confidentiality agreement and not discuss cases outside of the QPRC meeting to maintain protection from legal discovery.

As an ambulatory surgery center licensed by the Kansas Department of Health and Environment, the PPGP/CHPPGP is required to have a written risk management plan that is approved by the Board of Directors and submitted to KDHE annually (K.S.A. 65-492 and K.A.R. 28-52-1 through 28-52-4). The Risk Management Plan requires establishing a quarterly Peer Review meeting with at least 2 physicians. If there are fewer than 2 physicians on the CHPPGP ASC Medical Staff, KDHE requires the Peer Review Committee to procure an outside physician consultant.

Missouri also requires ambulatory surgery centers to have a Risk Management Plan. These plans are located: Q drive > Public Departments > Clinical Services > ALL Manuals> shortcut.

QPRC Procedure

- The QPRC is composed of the Medical Director and at least 1 additional physician.
- APRN/PAs are typically invited to attend the meetings and contribute.
- The CHPPGP Surgical Nurse Managers/CHPPGP Ambulatory Surgery Center Risk Managers attends and presents cases.
- The Director of CQRM drafts the agenda and records minutes.
- The QPRC members review the care provided and ask:
    - Was the complication or unwanted outcome known to be associated with the procedure
    - Was the complication recognized in a timely manner
    - Was the complication treated appropriately
    - Was the standard of care met
    - Was the complication part of a larger trend, and
    - Is there an opportunity for providers to improve the quality and safety of patient care?

The QPRC functions under the constructs of the Just Culture algorithm where the main focus is on learning and improving safety.

For CHPPGP cases, if the physicians find that the provider failed to meet the standard of care and the patient was harmed or was likely to have been harmed, the QPRC is required to report the case to KDHE. It is the policy of CHPPGP not to report cases to KDHE that did not occur in the ambulatory surgery center.

The state of Missouri requires abortion facilities in the state to report all complications. This requirement is described in the Missouri Risk Management Plan.

The Medical Director or Lead Clinician will assist practitioners who may require performance improvement activities.

The Medical Director or delegate will contact legal counsel where there may be an incident that is reportable to the state licensing agency or National Practitioner Data Bank.

Medical Director and Board of Director Review Schedule

Board of Directors appoint new CHPPGP Medical Staff Members for KS & MO	Review at Board meeting after completion of orientation, credentialing & privileging	Kansas Ambulatory Surgery Center Regulation 28-34-53
Board of Directors approve CHPPGP Risk Management Plan for KS & MO	Annually	Kansas Ambulatory Surgery Center Regulation 28-34-50(b)(1)
Medical Director & Lead Clinician approve MS&Gs	Annually	Required by PPFA as stated in Administrative chapter 1.

Resources

- Comprehensive Health of Planned Parenthood Great Plains Ambulatory Surgery Center Quality and Risk Management Plan (including pharmacy, lab and infection prevention)
- ARMS Credentials Verification: A Reference Guide for Planned Parenthood Affiliates
- PPFP Medical Director Orientation Manual (2014)
- PPFP Clinician Performance Monitoring Toolkit (2013)
- Kansas ASC Risk Management Planned Parenthood of Kansas and Mid-Missouri
- Missouri Abortion Facility Risk Management Plan
- Forms:
    - Clinician Skills Checklist: Proctoring Form
    - Clinical Privilege Form
    - Annual Clinician Performance Evaluation
    - Chart Review Form
    - OSHA evaluation

Exhibit 2

CLINICAL PRIVILEGING FORM

Colleen McNicholas has been granted clinical privileges for the following:

Date	Service	Signature of Medical Director or physician designee
4/15/15	X 1st trimester Surgical Abortion	
4/15/15	X Abortion pill	
4/15/15	X 2nd trimester Surgical abortion	
4/15/15	X Conscious Sedation	
	☐ Transabdominal Tubal Sterilization	
	☐ Hysteroscopic Tubal Sterilization	
	☐ Vasectomy	
	☐ Hysteroscopy	
	☐ LEEP	
	☐ Cryotherapy	
	☐ Colposcopy	
	☐ Endometrial Biopsy	
	☐ Vulvar Biopsy	
	☐ Fine Needle Aspiration	
	☐ Simple Cyst Aspiration	
4/15/15	X IUC Insertion	
4/15/15	X Implanon insertion	
	☐ Implant removal	
4/15/15	X Standard U/S (Abortion)	
4/15/15	X Limited U/S (Abortion)	
	☐ Standard U/S (Pregnancy)	
4/15/15	☐ Limited U/S (Pregnancy)	
	X Limited U/S for IUC localization	
	☐ Standard U/S (GYN)	
	☐	
	☐	
	☐	

List any formal training clinician received for service(s) noted above:

Service	Year	Length of Training	Didactic component	Clinical Component
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no

I have read and understand the _____ protocol. I agree to practice in accordance with this protocol when I am caring for clients at PHCM.

Clinician

Date

CLINICAL PRIVILEGING FORM

Ron Yeomans has been granted clinical privileges for the following:

Date	Service	Signature of Medical Director or physician designee
12/08/14	☑ Surgical Abortion	
	☐ Surgical Female Sterilization	
	☐ Essure	
	☐ Male Sterilization	
	☐ Hysteroscopy	
	☐ LEEP	
	☐ Cryotherapy	
	☐ Colposcopy	
	☐ Endometrial Biopsy	
	☐ Vulvar Biopsy	
	☐ Fine Needle Biopsy	
	☐ IUD insertion	
	☐ Implanon insertion and removal	
	☐ Norplant removal	
	☐ Standard U/S (Abortion)	
12/08/14	☑ Limited U/S (Abortion)	
	☐ Standard U/S (Pregnancy)	
	☐ Limited U/S (Pregnancy)	
	☐ Limited U/S for IUD localization	
	☐ Standard U/S (GYN)	
12/08/14	☑ Medical Abortion	
	☐ _____	
	☐ _____	

List any formal training clinician received for service(s) noted above:

Service	Year	Length of Training	Didactic component	Clinical Component
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no
			Yes/no	Yes/no

I have read and understand PP CHPPGP protocol. I agree to practice in accordance with this protocol when I am caring for clients at _____.

Ronald K. Yeomans, MD
Clinician

12/8/14
Date

Americans United for Life

Exhibit 3

Planned Parenthood®
Care. No matter what.

Planned Parenthood Great Plains

Policy: CLEANING THE ULTRASOUND PROBE AND CARE OF THE ULTRASOUND MACHINE

Originator: Kristin Metcalf-Wilson DNP, WHNP-BC

Approval Date: 04/01/2017

Policy:

Ultrasound machines constitute a significant resource investment for the agency. Although care must be taken with all aspects of the machine, the probes are especially delicate. Be sure to refer to the owner's manual/manufacturer's recommendations provided with the machine being used in the center.

The level of disinfection needed in between patients is determined by the route of scanning and the type of tissue contact. Transvaginal ultrasound constitutes endocavity scanning with mucous membrane contact and thus requires high level disinfection of the probe between patients. Although the use of probe covers may minimize probe contamination, the failure rate is surprisingly high and their use does not remove the need for high level disinfection. Abdominal scanning over intact skin poses little contamination risk, making a lower level of disinfection acceptable.

Process in the Clinics:

Starting the day

- Inspect all cords and probes for possible defects that may pose a safety hazard to the operator or patients.
- Ensure that any cords are tucked out of the way and uncoiled. Rolling over, stepping on or continuous tangling of the probe cords may damage the wires contained within the cords, causing imaging problems.
- Ensure proper supplies are available: ultrasound gel, non-latex sheaths and/or condoms for use with the vaginal probe, drape sheets, mild soap, cleaning agent(s) and soaking container, indicator strips and log for results, 2x4 labels, soft cloths, Resert XL HLD solution, and a timer.

General cleaning considerations

- All probes should be disconnected from the machine before they are cleaned to minimize safety hazards (i.e. shock to the operator, water damage to the machine).
- Although paper towels may be used to gently remove a soiled sheath, they should not routinely be used in any other part of the cleaning process. Paper towels are like sandpaper to the probe's delicate membrane surface.

- A soft cotton pile or microfiber cloth/towel should be used in any of the cleaning routines that follow. Although there are some disposable disinfecting wipes on the market, they do not provide the high level disinfection needed for the vaginal probe.
- A new cloth/towel is needed for every step in the process, so one should have access to at least three cloths per every scan. The microfiber towels (available at Costco or most automotive parts stores) can easily be cut into smaller squares (4 per towel) without fraying of the material.
- Launder cloths/towels according state guidelines and in a manner that maintains their softness. Towels that have lost their softness should be discarded as they may harm the probe membrane. Microfiber towels should not be exposed to fabric softener as it diminishes their absorptive abilities.

Resert XL HLD Solution for high level disinfection

Cleaning agents vary in the length of time needed to achieve high level disinfection, cost, and associated materials needed for the safe use of the cleaning agent. In an effort to provide high level disinfection in the least complicated manner and the shortest possible period of time, Resert is used to disinfect the probe.

Resert XL HLD is a ready to use, high level disinfecting solution. Unlike other high level disinfecting agents, it is virtually odorless, requiring no special ventilation, non-staining, and does not require special precautions (dilution or deactivation) for disposal.

Once poured into the soaking chamber, Resert XL HLD solution is good for up to 21 days of reuse provided that the minimum recommended concentration (MRC) of 1.5% is present, as verified by the approved indicator strips. A log of indicator results should be maintained.

The original open date should be recorded on the Resert XL HLD solution bottle using labels. The manufacturer's information indicates that the solution is good in the original container until the expiration date listed on the container. The soaking chamber should also have a center-applied label that lists the date the solution was poured into it, solution expiration date and the anticipated 21 day end of life date. At the start of every day, the solution must be tested with a Verify Chemical Monitoring Strip for Resert Solutions. Record the results of the test in the Resert Log. If the solution fails the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin. The solution should be covered at the end of every day. Please note that the color of the solution may change to light amber over time. This is not an indication of a problem as long as the MRC is verifiable.

Steris, maker of Resert XL HLD, suggests the following procedure for the using Verify Chemical Monitoring Strip for Resert Solutions:

- Ensure that the bottle of indicator strips is labeled with an open date. The strips expire 90 days from the open date or on the listed expiration date, whichever date comes first.
- Remove an indicator strip from the bottle. Dip the indicator pad into the soaking solution for 2 seconds, blot any excess by touching the edge of the pad to a paper towel, and then lay flat with the indicator pad facing up for 90 seconds, using a timer to monitor. Compare strip to color reference on the bottle.
- At the end of 90 seconds, read and record the result in the appropriate log. A "pass" is indicated by a color change from yellow to black. A "fail" is indicated by any blue or yellow remaining on the pad after 90 seconds.

- If the solution "fails" the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin.
- Controls should be run upon opening any new bottle of indicator strips.
    - For the positive control, dispense approximately 30mL of Resert XL HLD solution from an unopened bottle into a clean container. Run three test strips as per usual routine. All three strips must "pass."
    - For the negative control, dispense 15mL of Resert XL HLD solution from an unopened bottle into a clean plastic bottle, add 15mL of tap water to the bottle, and gently mix. Run three test strips as per usual routine. All three test strips must "fail."
    - If all six strips result as expected, the new bottle of Verify Chemical Monitoring Strip for Resert Solution may be used until the listed expiration date, whichever comes first. Be sure to record the open and controls run date on the bottle itself and in the log.
- Check state and local disposal regulations. Any expired or "failing" solution may be disposed of by flushing down the drain with water. The original container should be triple rinsed with water before tossing. Consult the MSDS for first aid measures. The indicator strips contain dye that may stain once activated but otherwise require no special precautions.

Cleaning of the vaginal probe

- Begin the day by testing the soaking solution to ensure that the MRC is met and verify that it is within the 21 day reuse range. Document results in the appropriate log.
- After scanning, unplug the probe from the machine and set the connector (plug) in the holder on the mounting kit that houses the soaking cup.
- Remove the contaminated probe cover with a paper towel and discard. Rinse the probe under water to remove any excess gel.
- Gently and thoroughly clean the probe using mild dish soap and a soft cloth, then rinse with running water, and dry with a clean soft cloth. Drying is important because it prevents progressive dilution of the soaking solution.
- Gently immerse the probe in the Resert XL HLD solution for eight minutes, using a timer to verify appropriate time interval. The immersion should include the entire transducer shaft (up to the ring that divides the handle from the transducer shaft) but none of the handle. See diagram in the manufacturer's probe brochure. The probe should not be left soaking any longer than the recommended eight minutes, as this may damage the probe covering.
- Rinse well with running water and dry using a clean soft cloth.
- Plug the connector back into the machine. The probe is now ready for use with the next patient.
- Note the aforementioned cleaning regimen requires the use of three soft cloths/towels per each probe disinfection and at least five minutes to elapse on the timer before calling back a new patient.

Cleaning of the abdominal probe

Abdominal probes should be cleaned and disinfected but do not generally require high level disinfection between patients.

- Remove any excess gel from the sides of the abdominal probe with a clean soft cloth. Spray probe with an ultrasound disinfectant detergent such as T-Spray and wipe thoroughly with a clean soft cloth.
- For this process, the abdominal probe does not need to be disconnected from the ultrasound machine.

Cleaning at the end of the day

Perform an extra cleaning of the probes at the end of the day to ensure equipment is left in optimal condition and ready to use. The Resert XL HLD solution should be covered. Launder any used cloths according to center and state guidelines.

Miscellaneous cleaning and service

Dust all areas of the machine twice per month or as needed with a lightly damp cloth. This is most easily accomplished with the machine turned off. The trackball may be removed and cleaned as need.
The screen may be cleaned using an alcohol swab and a soft cloth or Kimwipes. This task is best performed with the machine turned off and by working in quadrants so as to avoid streaking.

Annual maintenance of the machines may be provided by a manufacturer representative.

If trouble call service is needed, please contact agency resources to determine if the issue can be solved internally (IT or other staff) or requires a service call from the manufacturer. Contact a member of leadership to determine if service charges from the manufacturer are acceptable as the minimum trip charges are quite high.

Exporting files for storage

Files should be exported to CD/DVD or deleted from ultrasound machine hard drive storage before 50% of the hard drive capacity is exceeded. Failure to do so may result in sluggish performance of the machine.

Reference: ARMS Infection Prevention Manual

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The Department received the supplemental information you sent in regards to the remaining items cited at the October 2016 licensure survey of the Kansas City location (Brous Center). We request some additional clarification/information as follows:

19 CSR 30-30.0601(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.

- The facility failed to establish a traffic pattern in the decontamination/sterilization room that prevented cross contamination between contaminated and clean instrument processing. **Clarification/question: It is not entirely clear in the photos you supplied where the decontamination is being performed. Is it still be done in the same room as during the October 2016 visit? If the room remains the same as during our visit, have you have moved the autoclave to the center of the room so decontamination is carried out as staff enters, so traffic does not crossover and increase the chance of cross contamination? There was some discussion during our visit that the room might be relocated, or at least traffic patterns altered. Could you clarify? It might help to include a rough diagram of any changes made to the room or location or traffic pattern.**
- Decontamination is currently being performed in the same room as the October 2016 visit. The autoclave has been moved to the end of the counter and staff perform decontamination upon entering the room, so that cross contamination does not occur. Please see Exhibit 1, which is a diagram that illustrates the current traffic pattern.

- The facility failed to establish a policy for the process of high level disinfection of semi-critical instruments and equipment using OPA (ortho-phthalaldehyde) solution that included cleaning, disinfecting, rinsing, drying and storage.
Clarification/question: The procedure for high level disinfection (HDL) contains a back-up procedure that consists of soaking vaginal probes in a bleach solution. Bleach is not an FDA-approved HLD. For reference see:
https://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm
PPGP removed the use of bleach as a back-up high level disinfectant in the Cleaning the Ultrasound Probe and Care of the Ultrasound Machine Policy. All health centers performing ultrasounds will keep an adequate amount of Resert in stock, so that no back-up is needed. Please see Exhibit 2 for updated policy.

- The facility failed to ensure staff followed the policy for utilization of PPE (personal protective equipment) during decontamination of soiled instruments. The appropriate PPE was not available in the instrument decontamination/sterilization room. **Clarification/question: We did not see that this item was addressed; did we overlook it in your response? If so, please note where it is found.**
A picture of the available PPE was included in the letter dated 5/16/17 (Exhibit B) along with staff training materials. PPEs available for staff include face masks,

utility gloves. aprons and goggles/eye protection. Please see Exhibit 3 for an updated picture of PPE.

- The facility failed to follow safe medication practices by storing medications in the decontamination/sterilization room, and storing medications side by side in the refrigerator and locked cabinet with laboratory reagents and miscellaneous supplies. **Clarification/question: Blood Glucose reagents may be stored with medications but other reagents and lab specimens cannot be stored with medications (typically needs to be different refrigerator, not different shelf in the same refrigerator.)**
- PPGP has purchased an additional refrigerator to store reagents and lab specimens. Medication will be stored in a separate refrigerator. Please see Exhibit 4 for receipt for purchase of refrigerator.

- The facility stored supplies in corrugated boxes in the decontamination/sterilization room. **Clarification/question: We did not see that this item was addressed; did we overlook it in your response? If so, please note where it is found.** PPGP addressed corrugated cardboard boxes in the 5/16/17 letter in Exhibit F, which was pictures showing that there was no corrugated cardboard in the decontamination/sterilization room. Currently supplies are being removed from corrugated cardboard boxes and stored in Rubbermaid containers. Please see additional attached pictures in Exhibit 5.

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Exhibit 1

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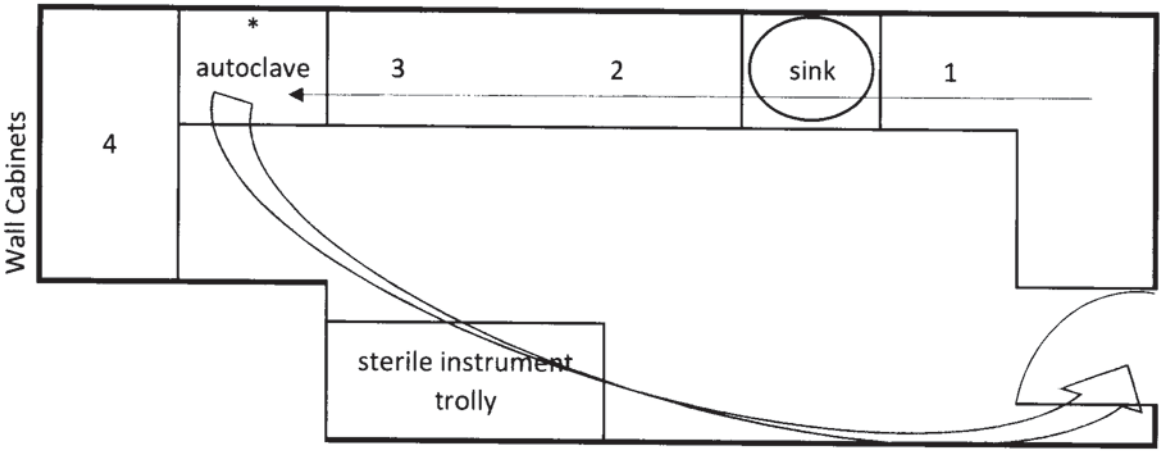
Traffic Pattern in Instrument Processing Room at Patty Brous



1 Soiled instrument deposited in basin
instruments washed in sink
2 instrument drying rack
3 clean area
4 clean instruments wrapped & labeled for autoclave
autoclave unloaded and sterile instruments are placed on wheeled trolly and taken to instrument storage areas
note: autoclave cannot be moved to opposite wall because there is no electric outlet there and the autoclave cord is not long enough to snake along wall to nearest electric outlet. Autoclave will not fit underneath the wall cabinets. Patty Brous will only offer medical abortions so there will be very few instruments to process.

Exhibit 2

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Planned Parenthood Great Plains

Policy: CLEANING THE ULTRASOUND PROBE AND CARE OF THE ULTRASOUND MACHINE

Originator: Kristin Metcalf-Wilson DNP, WHNP-BC

Approval Date: 04/01/2017

Policy:

Ultrasound machines constitute a significant resource investment for the agency. Although care must be taken with all aspects of the machine, the probes are especially delicate. Be sure to refer to the owner's manual/manufacturer's recommendations provided with the machine being used in the center.

The level of disinfection needed in between patients is determined by the route of scanning and the type of tissue contact. Transvaginal ultrasound constitutes endocavity scanning with mucous membrane contact and thus requires high level disinfection of the probe between patients. Although the use of probe covers may minimize probe contamination, the failure rate is surprisingly high and their use does not remove the need for high level disinfection. Abdominal scanning over intact skin poses little contamination risk, making a lower level of disinfection acceptable.

Process in the Clinics:

Starting the day

- Inspect all cords and probes for possible defects that may pose a safety hazard to the operator or patients.
- Ensure that any cords are tucked out of the way and uncoiled. Rolling over, stepping on or continuous tangling of the probe cords may damage the wires contained within the cords, causing imaging problems.
- Ensure proper supplies are available: ultrasound gel, non-latex sheaths and/or condoms for use with the vaginal probe, drape sheets, mild soap, cleaning agent(s) and soaking container, indicator strips and log for results, 2x4 labels, soft cloths, Resert XL HLD solution, and a timer.

General cleaning considerations

- All probes should be disconnected from the machine before they are cleaned to minimize safety hazards (i.e. shock to the operator, water damage to the machine).
- Although paper towels may be used to gently remove a soiled sheath, they should not routinely be used in any other part of the cleaning process. Paper towels are like sandpaper to the probe's delicate membrane surface.

- A soft cotton pile or microfiber cloth/towel should be used in any of the cleaning routines that follow. Although there are some disposable disinfecting wipes on the market, they do not provide the high level disinfection needed for the vaginal probe.
- A new cloth/towel is needed for every step in the process, so one should have access to at least three cloths per every scan. The microfiber towels (available at Costco or most automotive parts stores) can easily be cut into smaller squares (4 per towel) without fraying of the material.
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Resert XL HLD Solution for high level disinfection

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Resert XL HLD is a ready to use, high level disinfecting solution. Unlike other high level disinfecting agents, it is virtually odorless, requiring no special ventilation, non-staining, and does not require special precautions (dilution or deactivation) for disposal.

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- If the solution "fails" the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin.
- Controls should be run upon opening any new bottle of indicator strips.
    - For the positive control, dispense approximately 30mL of Resert XL HLD solution from an unopened bottle into a clean container. Run three test strips as per usual routine. All three strips must "pass."
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Cleaning of the vaginal probe

- Begin the day by testing the soaking solution to ensure that the MRC is met and verify that it is within the 21 day reuse range. Document results in the appropriate log.
- After scanning, unplug the probe from the machine and set the connector (plug) in the holder on the mounting kit that houses the soaking cup.
- Remove the contaminated probe cover with a paper towel and discard. Rinse the probe under water to remove any excess gel.
- Gently and thoroughly clean the probe using mild dish soap and a soft cloth, then rinse with running water, and dry with a clean soft cloth. Drying is important because it prevents progressive dilution of the soaking solution.
- Gently immerse the probe in the Resert XL HLD solution for eight minutes, using a timer to verify appropriate time interval. The immersion should include the entire transducer shaft (up to the ring that divides the handle from the transducer shaft) but none of the handle. See diagram in the manufacturer's probe brochure. <u>The probe should not be left soaking any longer than the recommended eight minutes, as this may damage the probe covering.</u>
- Rinse well with running water and dry using a clean soft cloth.
- Plug the connector back into the machine. The probe is now ready for use with the next patient.
- Note the aforementioned cleaning regimen requires the use of three soft cloths/towels per each probe disinfection and at least five minutes to elapse on the timer before calling back a new patient.

Cleaning of the abdominal probe

Abdominal probes should be cleaned and disinfected but do not generally require high level disinfection between patients.

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- For this process, the abdominal probe does not need to be disconnected from the ultrasound machine.

Cleaning at the end of the day

Perform an extra cleaning of the probes at the end of the day to ensure equipment is left in optimal condition and ready to use. The Resert XL HLD solution should be covered. Launder any used cloths according to center and state guidelines.

Miscellaneous cleaning and service

Dust all areas of the machine twice per month or as needed with a lightly damp cloth. This is most easily accomplished with the machine turned off. The trackball may be removed and cleaned as need.
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Files should be exported to CD/DVD or deleted from ultrasound machine hard drive storage before 50% of the hard drive capacity is exceeded. Failure to do so may result in sluggish performance of the machine.

Reference: ARMS Infection Prevention Manual

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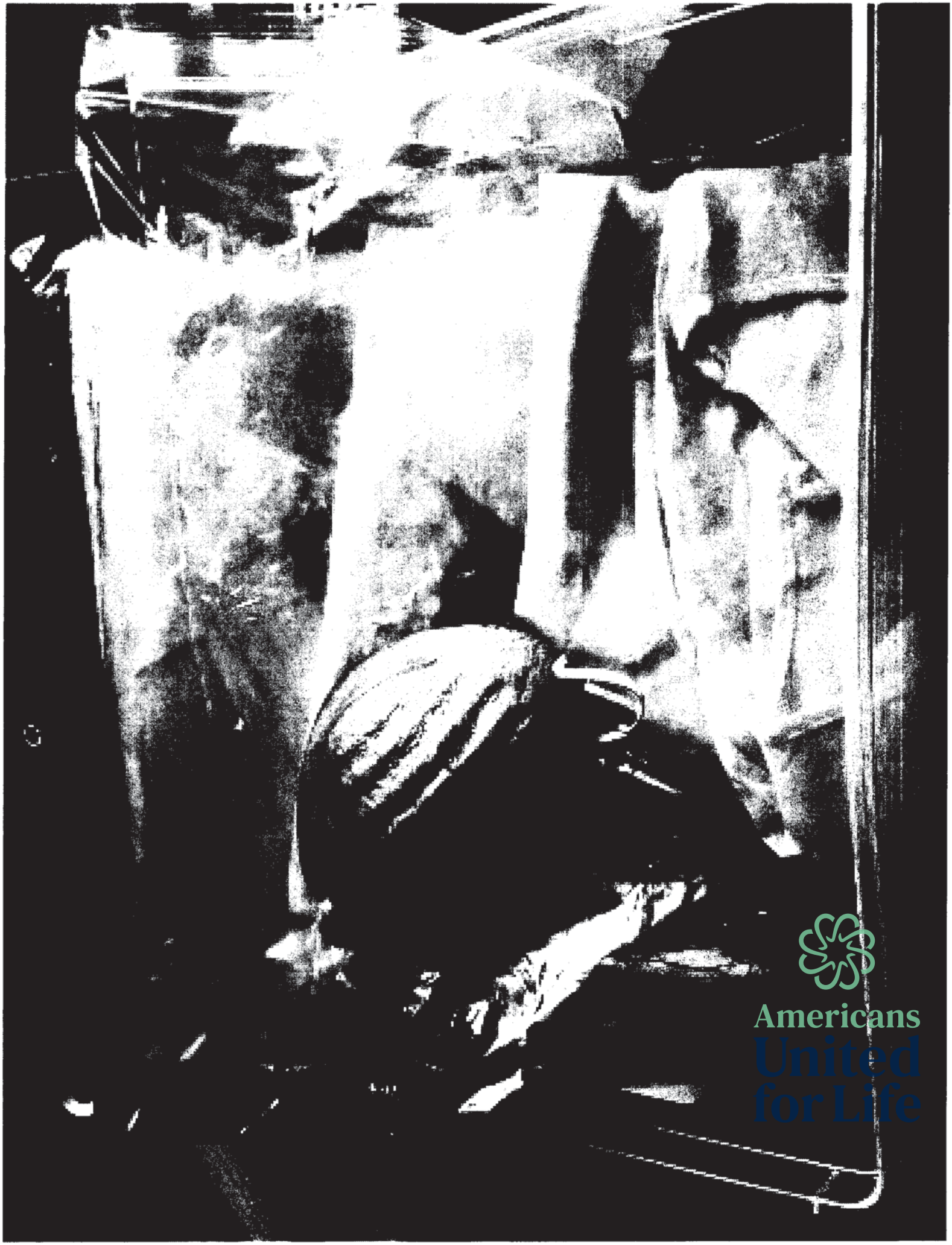
Exhibit 3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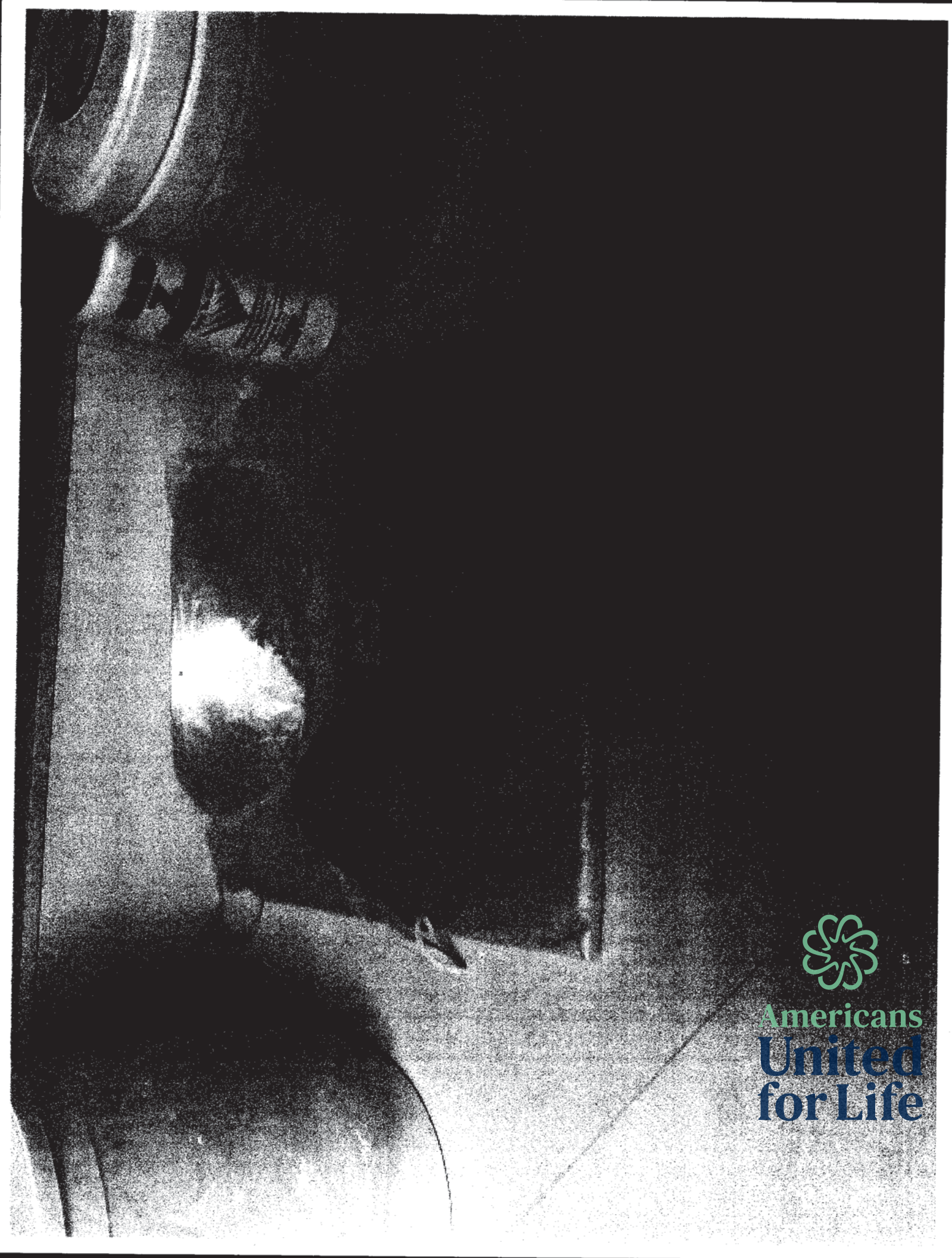
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Exhibit 4

See back of receipt for your chance to win $1000

ID #: 7LQVQ5VZOFH

Walmart

Save money. Live better.

(913) 296 - 0890
MANAGER MICHELLE MORALES
5150 ROE BLVD
ROELAND PARK KS 66205
STR 02490 OPR 009075 TE# 08 TR# 05694
1.7 C.F. BLK 083632100739 79.84 X
2YR RPL PLAN 060638822149 7.00 X
POWER STRIP 082721400568 19.84 X
SUBTOTAL 106.68
TAX 1 10.225 % 10.91
TOTAL 117.59
AMEX TEND 117.59
AMERICAN EXPRESS *** **** ***1 004 I 0
APPROVAL # 865650
REF # 000100269652
TRANS ID - 000965625981489

AID A0000000250108O1
TC 9A69C25A43CBEC85
TERMINAL # 285365921
*Signature Verified

05/31/17 12:46:20
CHANGE DUE 0.00
ITEMS SOLD 3
TC# 6060 6671 3618 8577 1945 0

Low Prices You Can Trust. Every Day.
05/31/17 12:46:20
CUSTOMER COPY

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Exhibit 5


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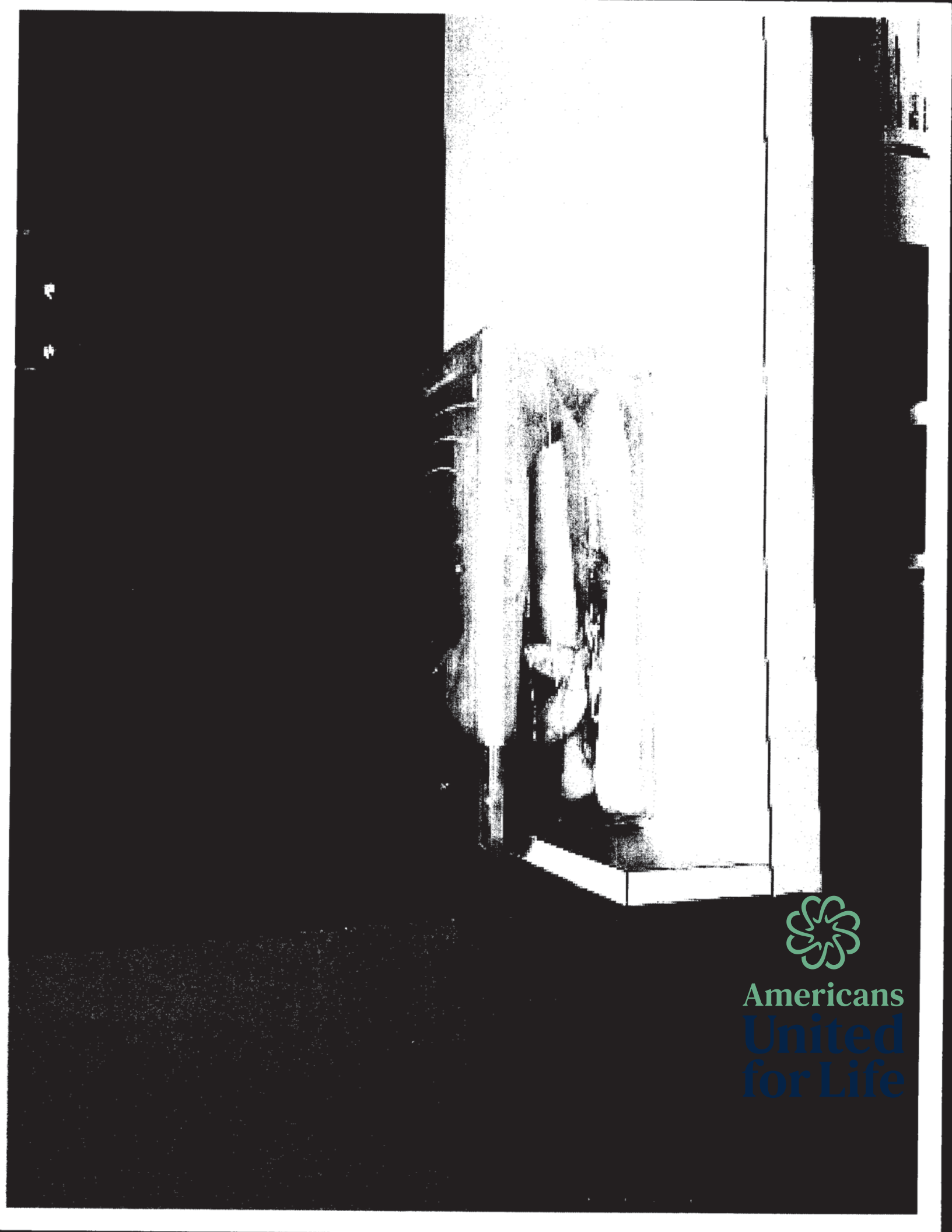
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for Life

Planned Parenthood®
Care. No matter what.

Comprehensive Health
4401 W. 109th St Suite 100
Overland Park, KS 66211
p: 913.345.1400 f: 913.345.2820
www.PPGreatPlains.org

Comprehensive Health of
Planned Parenthood Great Plains

May 16, 2017

John Langston
Bureau of Ambulatory Care
MO Department of Health & Senior Services
POB 570
Jefferson City MO 65102

Dear Mr Langston:

Please find attached our responses to the items that were found noncompliant at the October 2016 survey done at Comprehensive Health – Columbia location.

1. Credentialing packet for Dr Coleen McNicholas and Dr Ronald Yeomans
   Exhibit 1
   - Corporate Board Resolution/Medical Staff Approval to Practice (Physicians)
   - BNDD Certifications
   - DEA Certifications
   - Copies of National Practitioner's Data Bank check
   -
2. Limiting medical staff membership to physicians only
   Exhibit 2
   - Licensed Independent Providers Policies & Procedure from PPGP/CH Operations Manual

3. Pathology Contract
   Exhibit 3
   - Finalized pathology contract with Boyce & Bynum

4. Infection Control
   Exhibit 4
   - Copy of Autoclave Log
   - Packing slips for high level disinfecting supplies for ultrasound vaginal probe
   - Copy of PPGP/CH procedure for high level disinfecting

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5. Quality Assurance Program
   Exhibit 5
   - Copy of Quality Assurance & Risk Management Plan containing all elements required by Missouri abortion regulations
   -

6. Pathology –
   Exhibit 6
   - Copies of packing slips for 10% Formalin preservative solution
   - Picture of refrigerator to be used only for POC specimens

   **All POC's will be sent to pathology for disposal. No agreement with a waste sterilizer approved by the Dept of Natural Resources needed.

7. Anti-Rh Immune Globulin Therapy
   Exhibit 7
   - McKesson packing slip for MicroGAM

8. Supplies
   Exhibit 8
   - Supply list for medical and surgical abortions attached
   - Crash Cart checklist

9. Physician Hospital Privileges
   Section 060(1)(C)(4) of the organizational and management of abortion facilities is enjoined. Sections 188.027 and 188.080, RSMo, are enjoined.

10. Recovery Room Chairs
    070(2)(N) physical facility requirements are enjoined.

11. Recovery Room Exhaust Fan
    070(2)(X) physical facility requirements are enjoined.

Please let me know if you need anything further.

Sincerely,

Amanda Addison
Vice President of Health Services
Planned Parenthood Great Plains
amanda.addison@ppgreatplains.org
PH: 913-345-4659

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EXHIBIT 1

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Comprehensive Health of
Planned Parenthood Great Plains

CORPORATE BOARD RESOLUTION

Medical Staff Approval to Practice - Physicians

Based on successful credentialing by Medversant and skills assessment performed by the Medical Director or designee, the following provider(s) have been approved by the Comprehensive Health medical committee for privileges to practice at Comprehensive Health. These name(s) are respectfully submitted to the Comprehensive Health of Planned Parenthood Great Plains, Inc. Board of Directors for approval to practice. The following medical staff has agreed to conform with the bylaws of the governing authority and practice within the scope of the medical policies and protocols approved by the Medical Director.

I HEREBY CERTIFY that at a meeting of the Board of Directors of **Comprehensive Health of Planned Parenthood of Great Plains, Inc. (CHPPGP)**, a corporation organized and existing under and by virtue of the laws of the State of Missouri, held on the 6th day of December, 2016, at which said meeting a quorum was present and acting throughout, the following resolution was adopted and ever since has been and now is in full force and effect.

RESOLVED, that the Board of Directors of CHPPGP hereby approves the following medical staff to practice medicine:

Dr. Orrin Moore, MD
Overland Park, KS
Kansas City, MO

Dr. Laura Arrowsmith, DO
Tulsa, OK

Dr. Irene Bettinger, MD
Overland Park, KS
Kansas City, MO

Dr. Andrew Broselow, MD
Oklahoma City, OK
Wichita, KS

Dr. Elizabeth Campbell, DO
Tulsa, OK
Fayetteville, AR

Dr. Stephanie Ho, MD
Dr. Colleen McNicholas, DO
Columbia, MO

Dr. Jennifer Nelson, MD
Oklahoma City, OK

Dr. Clyde Rodgers, Jr. MD
Little Rock, AR

Dr. Ronald Yeomans, MD
Overland Park, KS
Wichita, KS
Kansas City, MO
Columbia, MO

In witness whereof, I have hereunto set my hand this 6th day of December 2016.

Marjorie Sable
Marjorie Sable
Board Secretary

MCNICHOLAS, COLLEEN P
711 PROVIDENCE ROAD
COLUMBIA, MO 65203-4357-000

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM5595573	01-31-2019	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	PRACTITIONER	10-06-2015

MCNICHOLAS, COLLEEN P
711 PROVIDENCE ROAD
COLUMBIA, MO 65203-4357

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM5595573	01-31-2019	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	PRACTITIONER	10-06-2015

MCNICHOLAS, COLLEEN P
711 PROVIDENCE ROAD
COLUMBIA, MO 65203-4357

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (4/07)

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	MCNICHOLAS, COLLEEN PATRICIA
BNDD Number:	2500031106
Description:	DOCTOR OF OSTEOPATHY
Street Address:	711 N PROVIDENCE RD
City/State/Zip:	COLUMBIA, MO 65203.4357
Phone Number:	573-443-0427
Registration Effective:	11/11/2016
Registration Expires:	11/30/2017
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	

Validation Date of the Registration is: 11/18/2016

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000117415258
Process Date: 12/06/2016
Page: 1 of 1
MCNICHOLAS, COLLEEN
For authorized use by:
PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

MCNICHOLAS, COLLEEN - ONE-TIME QUERY RESPONSE

Practitioner Name:	MCNICHOLAS, COLLEEN
Date of Birth:	12/10/1980 **Gender:** FEMALE
Organization Name:	PPGP
Work Address:	4401 W 109TH ST STE 200, OVERLAND PARK, KS 66211-1303
Social Security Number:	***-**-2828
License:	OSTEOPATHIC PHYSICIAN (DO)

Statutes Queried:	Title IV; Section 1921; Section 1128E
Query Type:	This is a One-Time query response. Your organization will only receive future reports on this practitioner if another query is submitted.
Entity Name:	PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI (DBID ending in ...54)
Authorized Submitter:	JANET SMITH, DIRECTOR OF COMPLIANCE AND QUALITY RISK, (913) 345-4609

The following report types have been searched:

Medical Malpractice Payment Report(s):	No Reports	Health Plan Action(s):	No Reports
State Licensure Action(s):	No Reports	Professional Society Action(s):	No Reports
Exclusion or Debarment Action(s):	No Reports	DEA/Federal Licensure Action(s):	No Reports
Government Administrative Action(s):	No Reports	Judgment or Conviction Report(s):	No Reports
Clinical Privileges Action(s):	No Reports	Peer Review Organization Action(s):	No Reports

---------- **No Reports Found** ----------

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FY6465012	05-31-2019	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5.	PRACTITIONER	12-01-2016

YEOMANS, RONALD N (MD)
711 N. PROVIDENCE ROAD
COLUMBIA, MO 65203-4357

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6321 Fax: 573-526-2569

Bureau of Narcotics and Dangerous Drugs
Missouri Department of Health and Senior Services

MISSOURI CONTROLLED SUBSTANCES REGISTRATION

This registration is not transferable

Registrant Name:	YEOMANS, RONALD N
BNDD Number:	2500037739
Description:	MEDICAL DOCTOR
Street Address:	711 N PROVIDENCE RD
City/State/Zip:	COLUMBIA, MO 65203.4357
Phone Number:	573-875-4177
Registration Effective:	11/3/2016
Registration Expires:	11/30/2017
BNDD Discipline:	NO
Drug Schedule Type:	2 3 4 5
Enrollment Date:	11/3/2016

Validation Date of the Registration is: 4/28/2017

Direct Inquiries to:

BNDD
PO BOX 570
Jefferson City, Missouri 65102 0570

NATIONAL PRACTITIONER DATA BANK

NPDB

P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000114513116
Process Date: 10/18/2016
Page: 1 of 1
YEOMANS, RONALD
For authorized use by:
PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI

YEOMANS, RONALD - ONE-TIME QUERY RESPONSE

Practitioner Name:	YEOMANS, RONALD
Date of Birth:	12/08/1940 **Gender:** MALE
Organization Name:	PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI
Organization Type:	AMBULATORY SURGICAL CENTER (391)
Work Address:	4401 W 109TH ST STE 200, OVERLAND PARK, KS 66211-1303
Social Security Number:	***-**-3082 **NPI:** 1417018557
License:	PHYSICIAN (MD), 04-14015, KS

Statutes Queried:	Title IV; Section 1921; Section 1128E
Query Type:	This is a One-Time query response. Your organization will only receive future reports on this practitioner if another query is submitted.
Entity Name:	PLANNED PARENTHOOD OF KANSAS AND MID-MISSOURI (DBID ending in ...54)
Authorized Submitter:	JANET SMITH, DIRECTOR OF COMPLIANCE AND QUALITY RISK, (913) 345-4609

The following report types have been searched:

Medical Malpractice Payment Report(s):	No Reports	Health Plan Action(s):	No Reports
State Licensure Action(s):	No Reports	Professional Society Action(s):	No Reports
Exclusion or Debarment Action(s):	No Reports	DEA/Federal Licensure Action(s):	No Reports
Government Administrative Action(s):	No Reports	Judgment or Conviction Report(s):	No Reports
Clinical Privileges Action(s):	No Reports	Peer Review Organization Action(s):	No Reports

---------- **No Reports Found** ----------

Americans United for Life

EXHIBIT 2

Americans United for Life

Licensed Independent Providers Policies & Procedures

Medical Staff

The Medical Staff is a formal organization of physicians who are appointed by the Board of Directors to provide patient care at Comprehensive Health of Planned Parenthood ambulatory surgery centers. The Medical Staff and Board of Directors collaborate to enhance the quality and safety of care, treatment, and services provided to patients. As an ambulatory surgery center licensed by the Kansas Department of Health and Environment in Kansas and Department of Health and Senior Services in Missouri (19 CSR 30-30.060), CHPPGP is required to have a Medical Staff of one or more physicians in Kansas (Kansas Ambulatory Surgery Center Regulations 28-34-50(b)(1) and three or more physicians in Missouri.

Medical Staff Membership

All physicians who work at CHPPGP are Medical Staff members. At PPGP/CHPPGP, the credentialing application is also the application for CHPPGP Medical Staff membership.

Medical Staff Bylaws for the CHPPGP ASC Medical Staff are located in the PPFA Medical Director Orientation Manual (2014) and Clinician Performance Monitoring Toolkit (2013).

CHPPGP Medical Staff Meetings occur quarterly immediately following the All-Staff meeting and are led by the Medical Director with administrative assistance to draft the agenda, send meeting invitations, record attendance and draft the minutes. The minutes are approved by the Medical Director. The CHPPGP Medical Staff members may invite other licensed independent providers (LIP), including advance practice registered nurses and physician assistants, to attend the Medical Staff meeting.

Medical Director

The Medical Director supervises all aspects of medical care at PPGP/CHPPGP. The Medical Director's responsibilities include performing or delegating the following:

- Leads the CHPPGP Medical Staff
- Oversees family planning, abortion and colposcopy programs
- Implements and updates the Medical Standards and Guidelines (MS&Gs)
- Develops or approves medical and clinical policies & procedures
- Ensures provider orientation, education, privileging, periodic chart review, and annual Ongoing Professional Practice Evaluation (OPPE) occur
- Establishes relationships within the medical community and participates in formulation of the referral list
- Serves as Laboratory Director
- Leads the Quality/ Peer Review Committee
- Reviews significant medical incidents in STARS and makes recommendations
- Assists legal counsel in responding to State regulatory investigations

- Serves as the collaborative practice agreement physician in Kansas and Missouri
- Serves as the Ultrasound Director to ensure staff and physician training and competence
- Serves on the PPGP/CHPPGP Quality/Risk Management Steering Committee

Professional Credentialing Policy

PPGP/CHPPGP demonstrates its commitment to being a health care leader that provides a consistently high level of quality care to the community by ensuring that all professional staff possess the appropriate licensure, education and relevant training. PPGP/CHPPGP requires its licensed independent providers (LIPs), at a minimum, to possess the credentials delineated in the ARMS Clinical Performance Monitoring Toolkit (2013).

The Director of CQRM uses the PPFA/ARMs credentialing service to verify the credentials of all physicians, Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Registered Nurses (RNs) and Licensed Social Workers (LSWs). Verification is sought to confirm that the provider has the education, training, skill sets, judgment, character, integrity, ability to work with others, and practice patterns to provide patient care at PPGP/CHPPGP. Credentialing occurs at the time of hire. Re-credentialing occurs every 3 years thereafter. This process is called "professional" credentialing to distinguish it from the process of "insurance" credentialing, performed by the finance and billing department.

Credentialing Procedure

The Director of CQRM will:

- Coordinate with Human Resources so that new providers are given the credentialing application immediately at the time of hire because it takes from 15 to 30 days to verify credentials. The process must start immediately in order to be completed before orientation ends. A new LIP should not care for patients independently until credentials are verified or insurance carriers may not pay for the care.
- All new physicians, APRNs, PAs, RNs and LSWs must complete the credentialing application and return it with a curriculum vitae and their DEA number, if relevant, within 5 days of hire. All gaps in employment must be explained. ARMS requires the professional credentialing process to have begun within 10 days of hire in order for the provider to see patients. If the provider cannot work because he/she did not return the application on time, PPGP/CHPPGP may not pay the provider until the application is submitted.
- Upload the application and CV to the credentialing service.
- Complete the ARMS request for a certificate of insurance (COI) naming the provider.
- Purchase special professional liability insurance for Certified Nurse Midwives (CNMs) and physician assistants who practice in Kansas. The most affordable option has been to buy insurance through our agent with KaMMCO. CNMs and

physician assistants must have special insurance because Kansas makes them pay into the Kansas Health Care Stabilization Fund.

- Notify the insurance credentialer that the provider is onboarding and fill out the shared provider spreadsheet with NPI number, DEA number, date of birth, etc. The spreadsheet is here: Q drive > Credentialing folder. The insurance credentialer will enter the LIP into the CAQH database and credential the LIP with third party payers.
- Query the National Provider Data Bank (NPDB) and download the provider's report.
- Draft collaborative practice agreements (CPA) for APRNs in Kansas, Missouri and Arkansas. Best practice is for the APRN to sign contracts with both the collaborating physician and a backup collaborating physician.
- Remind APRNs who will be prescribing testosterone in Missouri to submit an application for Controlled Substance Prescriptive Authority and a Notice of Delegated Prescriptive Authority for Controlled Substances with the Missouri State Board of Nursing. Send the CPA physician 10% of charts and 20% of controlled substance prescriptions every 2 weeks for review if required by State law.
- Download the verified credential report when it is ready.
- Review report for adverse events and, if necessary, request additional information to understand them.
- Give the practitioner's report to Human Resources to put into the provider's file.
- Give the RN or LSW's report to the VP Clinical Services.
- If the new physician works in the Kansas ASC or a Missouri abortion facility, remind the Board of Directors to approve the Medical Staff appointment as required by Kansas and Missouri regulations.
- Note: The new clinician orientation process and checklist are located in the Operations Manual section on Staff Standards.

Re-Credentialing Process

ARMS requires all physicians, APRNs, PAs. RNs, and LSWs to re-credential every 3 years. The Director of CQRM will:

- Annually, request the ARMS credentialing service to provide a spreadsheet of all credentialed staff and note which ones are due for the 3-year re-credentialing.
- Ask these staff to complete the re-credentialing application and return it.
- Upload the completed application to the credentialing service.
- Check the practitioner's name in the NPDB.

Credential Maintenance Policy

It is the policy of PPGP/CHPPGP that each professional has the responsibility to renew her/his own licenses and certifications, that licensed staff do not provide patient care if a mandatory license or certification lapses, and that professionals who allow a license or certification to lapse are subject to disciplinary action. If a LIP provides patient care after their certification or license lapses, and the insurance company (including

Medicaid) denies the claim due to the lapse, the LIP may be asked to reimburse PPGP/CHPPGP for denied claim.

Credential Maintenance Procedure

PPGP/CHPPGP has a process to ensure that its health care providers maintain required licensure and certification.

- As a courtesy, professionals may be reminded to renew licenses and certifications 60 and 30 days before expiration. PPGP/CHPPGP assumes no responsibility if a license or certification expires.
- In Missouri, APRNs must:
  - fax their renewed certification to the Missouri State Board of Nursing
    - The fax number is: **573-522-2143**
  - save the fax confirmation receipt.
  - After sending the fax, APRNs will telephone the Missouri State Board of Nursing to confirm the Board received their certification renewal.
    - The phone number to call is: **573.751.0681**
  - The APRN will document this phone call and save the documentation because the Missouri State Board of Nursing has denied receiving several faxed certifications in 2015 and 2016.
- The Director of CQRM will search on line to make sure the appropriate licensing entity posted the renewal.
- The Director of CQRM will notify the VP of Health Clinical Services and the Revenue Cycle Director if a license or certification expires (Medicaid may not reimburse care provided by an LIP with expired credentials).

Privileging Policy

It is the policy of PPGP/CHPPGP that only those health professionals who by state law, education and training are qualified to perform a particular clinical function are allowed to do so. Specialized services must only be provided by clinicians who are trained and demonstrate proficiency in those specific areas. Examples include, but are not limited to, performing ultrasound, colposcopy and Norplant and IUC insertions and removals. Determining the competency of each clinician is the responsibility of the Medical Director for physicians or Lead Clinician for APRNs and PAs.

Privileging Process

Newly Hired Practitioner – all newly hired physicians and APRN/PAs must undergo a period of supervised practice called proctoring. Proctoring is required regardless of pay status (employed, contracted, volunteer), length of experience prior to joining, or length of service (ex. employed 5 years and begins providing colposcopies). Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and is delegated to the Lead Clinician for PA/APRNs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form located in the PPFA Clinician Performance Monitoring Toolkit.

Practitioners Seeking Additional Privileges will be proctored by a practitioner who is privileged to perform the procedure. Proctoring is tailored to the skill level of the provider and length is determined by the Medical Director for physicians and Lead Clinician for APRN/PAs.

- The proctor completes the Clinician Skills Checklist: Proctoring Form, located in the PPFA Clinician Performance Monitoring Toolkit.

Ongoing Professional Practice Evaluation Policy

It is PPGP/CHPPGP's policy to conduct ongoing professional practice evaluation (OPPE) at least annually to ensure clinicians are providing and documenting care consistent with the MS&Gs and the PPGP/CHPPGP mission. If OPPE reveals adverse data, the Medical Director will develop a performance improvement plan that may include altering the provider's privileges, additional proctoring, education, discipline, or termination, in order to ensure patient safety.

Ongoing Professional Practice Evaluation Procedure

PA/APRN OPPE

The Medical Director is responsible for APRN/PA OPPE but may delegate the review to the Lead Clinician. The Lead Clinician will report all findings to the Medical Director for final determination of competency. Competency will be evaluated within 3 months of hire and annually at a minimum.

Methods of review include:

- Chart Audit: The Lead Clinician will audit at least 10 patient charts for the PA/APRN annually and as needed.
- Observation: The Lead Clinician will observe the APRN/PA during orientation and annually. Areas of observation will include history taking, patient education, physical assessment, infection control, patient management, and charting.
- Microscopy: The Lead Clinician will assess Vaginal Wet Mount Microscopy accuracy semi-annually and will evaluate competency annually. At the annual evaluation, microscopy skills will be observed. In addition, at least 5 slides will be reviewed by the APRN/PA and the Lead Clinician with an expectation of 80% agreement. Semi-annually, the APRN/PA will be tested on reading at least 4 microscope photos with an expectation of 100% accuracy.
- Training and Meetings: PA/APRNs are expected to participate in PPGP/CHPPGP Leadership Team Meetings and training opportunities.
- Referral Protocol: The Lead Clinician will review APRN/PA compliance with the referral protocol via annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.
- Pap Protocol: PA/APRNs will be reviewed for compliance with the abnormal pap protocol. Review will be by annual audit with an expectation of 90% compliance to appropriate documentation and timely follow-up.

Lead Clinician OPPE

The Medical Director will perform the Lead Clinician's OPPE based on the above review methods. Additionally, the Lead Clinician will be evaluated on her/his oversight of the provision of clinic medical services, including APRN/PAs, medical assistants, RNs, LPNs, and student PA/APRNs. The Lead Clinician will be evaluated on how well she/he works with the clinic managers to communicate any changes in medical care and protocols to clinic staff.

Physician OPPE

The Medical Director is responsible for performing physician OPPE. Competency will be evaluated within 3 months of hire and annually. The Medical Director will employ the following methods of review:

- Observation: Areas of review will include surgical technique, communication with staff, professional rapport with patients and infection control.
- Chart Audit: Patient care chart audits of at least 10 charts will be performed annually and as needed to assure compliance with the MS&Gs. All areas of service the physician provides will be included. Areas of review will include consent, history, lab, assessment, plan, and referral.
- Risk Management: Physician complication statistics will be compiled annually and reviewed for trends by the Medical Director, staff physicians, Director of CHPPGP, and Director of Quality and Risk Management. An annual complication rate will be included in the annual physician review with an expectation of less than 2% complication rate.
- Training and Meetings: Physician is expected to participate in CME meetings and training opportunities.

Medical Director OPPE

The Medical Director's OPPE will be performed by an outside physician consultant. Additionally, the Medical Director will be evaluated on how well he/she fulfills the Medical Director job description.

Ultrasound Quality Improvement Program OPPE

PPGP has an ongoing ultrasound quality improvement program for all staff that performs ultrasounds that includes:

- Initial training
- Proctoring
- Privileging
- Monitoring
- Ongoing proficiency

All staff who perform ultrasounds for abortion care will demonstrate competence initially by completing the Ultrasound Privileging form (located in the PPFP Clinician Performance Monitoring Toolkit (2013), watching the CAL ultrasound videos, proctoring, an annual observation and annual chart review of 10 random chart by the Lead Clinician.

Quality/Peer Review Policy

Where OPPE occurs annually and examine the provider's competence, the Quality / Peer Review Committee (QPRC) meets quarterly and examines unwanted clinical outcomes for trends and opportunities for improvement. It is the policy of PPGP/CHPPGP for the QPRC to review all unwanted patient outcomes. The process is protected under state and federal physician peer review, quality improvement, and patient safety statutes. Each participant should sign a confidentiality agreement and not discuss cases outside of the QPRC meeting to maintain protection from legal discovery.

As an ambulatory surgery center licensed by the Kansas Department of Health and Environment, the PPGP/CHPPGP is required to have a written risk management plan that is approved by the Board of Directors and submitted to KDHE annually (K.S.A. 65-492 and K.A.R. 28-52-1 through 28-52-4). The Risk Management Plan requires establishing a quarterly Peer Review meeting with at least 2 physicians. If there are fewer than 2 physicians on the CHPPGP ASC Medical Staff, KDHE requires the Peer Review Committee to procure an outside physician consultant.

Missouri also requires ambulatory surgery centers to have a Risk Management Plan. These plans are located: Q drive > Public Departments > Clinical Services > ALL Manuals> shortcut.

QPRC Procedure

- The QPRC is composed of the Medical Director and at least 1 additional physician.
- APRN/PAs are typically invited to attend the meetings and contribute.
- The CHPPGP Surgical Nurse Managers/CHPPGP Ambulatory Surgery Center Risk Managers attends and presents cases.
- The Director of CQRM drafts the agenda and records minutes.
- The QPRC members review the care provided and ask:
    - Was the complication or unwanted outcome known to be associated with the procedure
    - Was the complication recognized in a timely manner
    - Was the complication treated appropriately
    - Was the standard of care met
    - Was the complication part of a larger trend, and
    - Is there an opportunity for providers to improve the quality and safety of patient care?

The QPRC functions under the constructs of the Just Culture algorithm where the main focus is on learning and improving safety.

For CHPPGP cases, if the physicians find that the provider failed to meet the standard of care and the patient was harmed or was likely to have been harmed, the QPRC is required to report the case to KDHE. It is the policy of CHPPGP not to report cases to KDHE that did not occur in the ambulatory surgery center.

The state of Missouri requires abortion facilities in the state to report all complications. This requirement is described in the Missouri Risk Management Plan.

The Medical Director or Lead Clinician will assist practitioners who may require performance improvement activities.

The Medical Director or delegate will contact legal counsel where there may be an incident that is reportable to the state licensing agency or National Practitioner Data Bank.

Medical Director and Board of Director Review Schedule

Board of Directors appoint new CHPPGP Medical Staff Members for KS & MO	Review at Board meeting after completion of orientation, credentialing & privileging	Kansas Ambulatory Surgery Center Regulation 28-34-53
Board of Directors approve CHPPGP Risk Management Plan for KS & MO	Annually	Kansas Ambulatory Surgery Center Regulation 28-34-50(b)(1)
Medical Director & Lead Clinician approve MS&Gs	Annually	Required by PPFA as stated in Administrative chapter 1.

Resources

- Comprehensive Health of Planned Parenthood Great Plains Ambulatory Surgery Center Quality and Risk Management Plan (including pharmacy, lab and infection prevention)
- ARMS Credentials Verification: A Reference Guide for Planned Parenthood Affiliates
- PPFP Medical Director Orientation Manual (2014)
- PPFP Clinician Performance Monitoring Toolkit (2013)
- Kansas ASC Risk Management Planned Parenthood of Kansas and Mid-Missouri
- Missouri Abortion Facility Risk Management Plan
- Forms:
    - Clinician Skills Checklist: Proctoring Form
    - Clinical Privilege Form
    - Annual Clinician Performance Evaluation
    - Chart Review Form
    - OSHA evaluation

EXHIBIT 3

LABORATORY SERVICES AGREEMENT

THIS AGREEMENT made this 2nd day of May 2017, by and between Comprehensive Health of Planned Parenthood Great Plains, ("CLIENT") and Boyce & Bynum Pathology Laboratories, P.C. ("LABORATORY").

WHEREAS, LABORATORY is engaged in the business of providing reference clinical laboratory services (the "Services"); and

WHEREAS, CLIENT desires to contract with LABORATORY to provide reference clinical laboratory services for CLIENT, and LABORATORY desires to provide the Services described herein.

IT IS THEREFORE AGREED AS FOLLOWS:

1. TERM AND TERMINATION

This Agreement shall become effective on the date set forth above and shall continue in effect until terminated by either party. This Agreement shall have an initial term of one (1) year ("Initial Term") and shall be automatically renewed for additional periods of one (1) year ("Renewal Term") at the end of the Initial Term or any Renewal Term, unless previously terminated by either party.

This Agreement may be terminated by either party, with or without cause, at any time, by giving the other party thirty (30) days prior written notice to the address set forth in Section 9.

2. TESTING SERVICES

LABORATORY agrees to perform such Services for CLIENT as may be requested by CLIENT, if available, during the term of this Agreement. The Services shall include those tests listed in LABORATORY's current Directory of Services, as the same may be modified from time to time by LABORATORY and such additional services as the parties may agree to in writing.

3. ADDITIONAL SERVICES

A. SPECIMEN PICK UP AND REPORT DELIVERY

LABORATORY will provide a reference specimen pick up and report delivery service to CLIENT on a daily basis Monday through Friday and Saturday as requested. LABORATORY shall make reasonable efforts to deliver or transmit results of a routine nature (general routine chemistries) to CLIENT within 24 hours of the time the specimen is received by LABORATORY's testing facility. LABORATORY shall make reasonable efforts to deliver or transmit results of tests performed on specimens of a special nature (special chemistries, tissues, etc.) to CLIENT within the times set forth in LABORATORY's then current turn-around-time schedule. LABORATORY shall report panic or critical values performed at LABORATORY facilities in a manner consistent with LABORATORY's standard policies and procedures. CLIENT hereby represents and warrants that it has reviewed such policies and procedures and further acknowledges that it understands and agrees with LABORATORY policies and procedures.

B. CONSULTATION

LABORATORY staff shall be available to consult with CLIENT by telephone during normal LABORATORY working hours to discuss LABORATORY's procedures and to provide the status of test results.

4. FEES

CLIENT agrees to pay, to the extent responsible for payment, for the Services provided under this Agreement the fees set forth in Exhibit A. CLIENT shall pay the greater of the fees listed in Exhibit A or the charges to LABORATORY for reference testing performed by a laboratory not owned by or affiliated with LABORATORY. In no event shall the fees paid to LABORATORY for reference testing performed by a laboratory not owned or affiliated with LABORATORY exceed agreed upon rate structure. After the Initial Term of this Agreement, CLIENT and LABORATORY agree that fees shall either increase on the renewal date hereof or with LABORATORY's general annual fee increase of which CLIENT shall receive thirty (30) days written notice. In no event shall a fee increase enacted on the renewal date exceed the LABORATORY'S general annual fee increase without the written consent of the CLIENT. CLIENT and LABORATORY acknowledge and agree that fees shall not be adjusted more frequently than once a year.

Notwithstanding the foregoing, CLIENT acknowledges that LABORATORY may develop and/or provide new technologies and/or new methodologies during the term of this Agreement. LABORATORY shall notify CLIENT when such technologies and/or methodologies are available and the fee associated with such technologies and/or methodologies. If, during the term of this Agreement, any nationally recognized professional medical association makes recommendations that establish or change a standard of care for testing, the parties will work in good faith to agree on an appropriate rate of payment for testing affected by the new or modified standard of care on a fee for service basis. If the parties cannot reach agreement, LABORATORY shall have the right to terminate this Agreement by giving thirty (30) days written notice to CLIENT.

5. BILLING

CLIENT shall indicate the entity responsible for payment of Services rendered on the requisition submitted to LABORATORY. CLIENT shall submit to LABORATORY 3rd party payment information for all patients with 3rd party coverage.

If CLIENT indicates that CLIENT is responsible for payment, LABORATORY will submit to CLIENT a monthly statement of Services rendered to CLIENT by LABORATORY for the prior month and CLIENT agrees to remit payment to LABORATORY for Services. Payment for Services is due thirty (30) days after the date of invoice. Failure to remit payment within said time may result, among other remedies available to LABORATORY, in discontinuation of Services. Nothing in the foregoing provision shall serve to waive any rights or remedies available to LABORATORY with respect to its providing Services to CLIENT. If LABORATORY is compelled to bring suit to collect amounts due hereunder LABORATORY shall be entitled to recover from CLIENT interest on amounts due in accordance with Missouri Revised Statute 408.040, reasonable attorney's fees and costs of suit incurred in connection with such action.

If CLIENT indicates that a third party is responsible for payment, LABORATORY, in accordance with legal and regulatory requirements, agrees to bill the patient or other responsible party, including Medicare, Medicaid and insurance companies, for Services performed under this Agreement. CLIENT agrees to promptly provide LABORATORY with all necessary information to accomplish the billing and collection of amounts due, including required diagnosis information. If LABORATORY is unable to obtain payment from any third party due to CLIENT's failure to provide the information required by this Agreement, or as a result of CLIENT's failure to follow applicable rules or regulations, CLIENT agrees to pay LABORATORY for all such Services.

6. ACCREDITATION OF TESTING SITES

The Services performed hereunder shall be performed at testing facilities to be selected by LABORATORY. LABORATORY's facilities are and shall remain duly licensed clinical laboratories under applicable federal, state and local law. Reasonable documentation of such credentials shall be provided upon written request.

7. CHANGE IN LAW OR REGULATION

The terms of this Agreement are intended to be in compliance with all federal, state and local statutes, regulations and ordinances applicable on the date the Agreement takes effect including but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Deficit Reduction Act of 2005 ("DRA"), and applicable State False Claims Acts ("SFCA"). The parties agree to execute amendments as may be necessary for the continuing compliance with the aforementioned Acts, as additional regulations are promulgated or become final and effective. Should either party reasonably conclude that any portion of this Agreement is or may be in violation of such requirements or subsequent enactments by federal, state or local authorities, or if any such change or proposed change would materially alter the amount or method of compensating LABORATORY for Services performed for CLIENT or for any other party under this Agreement, or would materially increase the cost of LABORATORY's performance hereunder, the parties agree to negotiate written modifications to this Agreement as may be necessary to establish compliance with such authorities or to reflect applicable changes.

8. NON-ASSIGNABILITY

This Agreement may not be assigned by either party without the written consent of the other party which consent shall not be unreasonably withheld or delayed.

9. NOTICES

Any notice required to be given pursuant to the terms and provisions hereof shall be in writing and shall be sent by certified or registered mail to LABORATORY at:

Boyce & Bynum Pathology Laboratories, P.C.
200 Portland St
Columbia, MO 65201
Attention: Compliance

and to CLIENT at:

Regional Director of Health Center Operations
Comprehensive Health of Planned Parenthood Great Plains
4401 W 109th St., Ste 200
Overland Park, KS 66211
Attention: Vicki Casey

10. INDEPENDENT RELATIONSHIP

None of the provisions of this Agreement are intended to create, nor shall be deemed or construed to create, any relationship between CLIENT and LABORATORY other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Agreement. Neither of the parties hereto, nor any of their respective employees shall be construed to be the agent, employer or representative of the other.

11. FORCE MAJEURE

Neither LABORATORY nor CLIENT shall be liable for any claims or damages and shall be excused for such claims, damages, failures and delays in the performance of its obligations under this Agreement due to any act or cause beyond the reasonable control and without the fault of LABORATORY or CLIENT including, without limitation, acts of God such as fire, flood, tornado, earthquake; acts of government (i.e., civil injunctions or enacted statutes and regulations); or acts or events caused by third parties such as riot, strike, power outage or explosion; or the inability due to any of the aforementioned causes to obtain necessary labor or materials.

12. WARRANTY

A. CLIENT WARRANTS TO LABORATORY THAT NEITHER CLIENT NOR ANY OF ITS EMPLOYEES OR OWNERS HAVE BEEN DEBARRED, SUSPENDED, DECLARED INELIGIBLE OR EXCLUDED FROM MEDICARE, MEDICAID OR ANY OTHER FEDERAL OR STATE GOVERNMENT HEALTHCARE PROGRAM.

B. LABORATORY WARRANTS TO CLIENT THAT NEITHER LABORATORY NOR ANY OF ITS EMPLOYEES OR OWNERS HAVE BEEN DEBARRED, SUSPENDED, DECLARED INELIGIBLE OR EXCLUDED FROM MEDICARE, MEDICAID OR ANY OTHER FEDERAL OR STATE GOVERNMENT HEALTHCARE PROGRAM.

C. LABORATORY WARRANTS TO CLIENT THAT ALL SERVICES PROVIDED HEREUNDER SHALL BE IN ACCORDANCE WITH ESTABLISHED AND RECOGNIZED CLINICAL LABORATORY TESTING PROCEDURES AND WITH REASONABLE CARE IN ACCORDANCE WITH APPLICABLE FEDERAL, STATE AND LOCAL LAWS AND REGULATIONS.

D. NO OTHER WARRANTIES ARE MADE BY LABORATORY.

E. NO OTHER WARRANTIES ARE MADE BY CLIENT.

F. IN NO EVENT SHALL LABORATORY OR PPSLRSWMO BE RESPONSIBLE FOR ANY PUNITIVE DAMAGES OR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, OR SPECIAL DAMAGES OF CLIENT OR OF ANY THIRD PARTY.

13. BENEFIT

This Agreement is intended to inure only to the benefit of LABORATORY and CLIENT. This Agreement is not intended to create, nor shall be deemed or construed to create, any rights in any third parties.

14. NONDISCRIMINATION

All Services provided by LABORATORY hereunder shall be in compliance with all applicable Federal and State laws, regulations and ordinances prohibiting discrimination on the basis of race, color, religion, sex,

national origin, handicap, veteran status or any other protected class.

15. HEADINGS

The headings in this Agreement are for convenience and reference only and are not intended to, and shall not, define or limit the scope of the provisions to which they relate.

16. ENFORCEABILITY/SEVERANCE CLAUSE

The invalidity or unenforceability of any term or provisions of this Agreement in any jurisdiction shall not affect the validity or enforceability of any of the other terms or provisions in that jurisdiction or of the entire Agreement in any other jurisdiction. If any provision is held invalid by a court of competent jurisdiction, such shall be severed and the Agreement shall be interpreted as though the severed provision had not existed.

17. WAIVER

No course of dealing between the parties or any delay on the part of either party in exercising any rights they may have under this Agreement shall operate as a waiver of any of the rights of the other party. No express waiver shall affect any condition, covenant, rule, regulation, right or remedy other than the one specified in such waiver and only for the time and in the manner specifically stated.

18. ACCESS TO BOOKS AND RECORDS

If the Services to be provided by LABORATORY hereunder are subject to the disclosure requirements of 42 U.S.C. 1395x (v) (1) (I), LABORATORY shall until expiration of ten (10) years make available, upon written request of the Secretary of Health and Human Services, or upon request to the Comptroller General, or any of their duly authorized representatives, a copy of this Agreement and the books, documents and records of LABORATORY that are necessary to certify the nature and extent of the costs incurred under this Agreement through a subcontractor with a value or cost of $10,000.00 or more over a twelve (12) month period. In addition, with respect to any applicable subcontract, such subcontract shall contain a clause to the effect that, should the subcontractor be deemed a related organization, until the expiration of six (6) years after the furnishing of services pursuant to such subcontract, the subcontractor shall make available upon written request of the Secretary of Health and Human Services, or upon request to the Comptroller General, or any of their duly authorized representatives, a copy of the subcontract, and the books, documents and records of such third party that are necessary to verify the nature and extent of the costs incurred under this Agreement. Should LABORATORY and/or a subcontract receive such a request, CLIENT shall be notified in writing of the request within five (5) days.

During the term of this Agreement, upon reasonable prior written request and during normal business hours, LABORATORY shall allow CLIENT reasonable access to LABORATORY records concerning the Services provided hereunder. CLIENT warrants and represents that it has obtained any necessary written consent from CLIENT patients for the release of such records. Such consent shall satisfy all applicable laws and regulations including but not limited to the privacy regulations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

19. MODIFICATION

This Agreement may only be modified in a writing signed by authorized representatives of each party.

20. ENTIRE AGREEMENT

This Agreement constitutes the entire understanding between the parties hereto concerning the subject matter herein and is a complete statement of the terms thereof and shall supersede all previous understandings between the parties, whether oral or written with respect to the subject matter herein. The parties shall not be bound by any representation made by either party or agent of either party that is not set forth in this Agreement. Any applicable provisions required by federal, state, or local law are hereby incorporated by reference.

21. GOVERNING LAW

This Agreement shall be construed under the laws of the State of Missouri.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in their names as their official acts by their respective representatives, each of whom is duly authorized to execute the same.

LABORATORY:
Boyce & Bynum Pathology Laboratories, P.C.

By: _____

Print Name: Richard Cotten

Date: 05/09/2017

CLIENT:

Comprehensive Health of Planned Parenthood Great Plains

By: _____

Print Name: Aaron Samulcek

Date: 5/9/17

Americans United for Life

EXHIBIT A
FEES

For the Services ordered by CLIENT and performed by LABORATORY that are not set forth attached, CLIENT agrees to pay the fees set forth in LABORATORY's current Professional Fee Schedule labeled Base 14 as modified from time to time by LABORATORY.

Americans United for Life

EXHIBIT 4

Americans United for Life

AUTOCLAVE LOG for Month Dec 2016

Clinic: Columbia

Biomedical company: BESS **Last Calibration Date:** 1

Date of Monthly Infection Prevention Maintenance (Clean, drain & replace water): 12/8/16

Dates of weekly spore testing & results:

date of week 1 12/6/16 (pass) / fail (circle one)

date of week 2 12/12/16 (pass) / fail (circle one)

date of week 3 12/22/17 (pass) / fail (circle one)

date of week 4 _____ pass / fail (circle one)

*Autoclave not working Dec 4th Week

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
12/6/16	1	Curved Forcep	1	FP	Pass	Pass	10:50AM	260°F	KPR
		Speculum	9	FP	Pass	Pass	10:50AM	260°F	KPR
12/7/16	1	Curved Forcep	2	FP	Pass	Pass	9:13AM	260°F	KPR
same time 12/7/16	1	Strait Forcep	4	FP	Pass	Pass	9:13AM	260°F	KPR
12/8/16	1	Speculum	10	FP	Pass	Pass	9:13AM	260°F	KPR
12/9/16	1	Curved Forcep	2	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Strait Forcep	2	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Ring Forcep	1	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	UVB Pack	2	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Speculums	4	FP	Pass	Pass	9:43AM	260°F	KPR
"	1	Long Strait Forcep	1	FP	Pass	Pass	9:43AM	260°F	KPR
12/12/16	1	Strait Long Forcep	1	FP	Pass	Pass	9:18AM	260°F	KPR

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
12/12/16	1	speculum	3	FP	Pass	Pass	9:18am	260°F	KPRW
12/16/16	1	IUD Pack	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	small straight forcep	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	small curved forcep	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	Colp Biopsy Punch tool	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/16/16	1	Colp Straight ends	2	FP	Pass	Pass	8:07am	260°F	KPRW
12/22/16	1	Specula	15	FP	pass	pass	12:50pm	260°F	MWelmaker
12/22/16		1 Sound	1	FP	pass	pass	12:50pm	260°F	MWelmaker
12/22/16		Curved straight forcep	1 each	FP	pass	pass	12:50pm	260°F	MWelmaker
1/3/17		Specula	8	FP	pass	pass	10:30am	260°F	MWelmaker
1/25/16	1	Specula		FP	Pass	Pass	9:30am	260°F	
1/25/16	1	Forceps		FP	Pass	Pass	9:30am	260°F	
1/25/17		Speculum		FP	Pass	Pass	5:30pm	260°F	
1/25/17		Speculum		FP	Pass	Pass	5:30pm	260°F	

AUTOCLAVE LOG for Month March

Clinic: Columbia

Biomedical company: BESS **Last Calibration Date:** QRM √ list

Date of Monthly Infection Prevention Maintenance (Clean, drain & replace water): 3/30/17

Dates of weekly spore testing & results:

date of week 1_____ **pass / fail (circle one)**

date of week 2_____ **pass / fail (circle one)**

date of week 3_____ **pass / fail (circle one)**

date of week 4_____ **pass / fail (circle one)**

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
3/9/17		Scan - 2 IUD packs	12	FP		pass	2:04	260°	
3/10/17		Speculum		FP		pass	9:03	260°	
"		Scissors	2	FP		pass	9:03	260°	
"		forcep Ring	1	FP		pass	9:03	260°	
3/10/17		2 IUD packs 1 scissors	3	FP		pass	11:4	260°	
3/10/17		4 alligator clamps	4	FP		pass	1:49p	260°	
"		2 Ring forcep	2	FP		pass	1:49p	260°	
"		IUD pack	1	FP		pass	1:49p	260°	
"		Alligator clamps	3	FP		pass	3:35p	260°	
"		tenaculum	1	FP		pass	"	260°	
"		Speculums	10	FP		pass	"	260°	
3/22/17		10 speculums	10	FP		Pass	9:42	260°	

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
3/23/17		IUC Pack	2	FP		pass	9:42	260°	
"		Ring forceps	2	FP		pass	9:42	260°	
"		Ring forcep	1	FP		pass	1:31p	260°	
"		sound	1	FP		pass	1:31p	260°	
"		Tenaculum IUC pack	1	FP		pass	1:31p	260°	
3/22		~~tenaculum~~	~~1~~			~~pass~~			
3/22		Specculums	9	FP		pass	1:31p	260°	
3/24/17		tenaculum	1	FP		Pass	2:03p	260°	
"		specculums	10	FP		pass	2:03p	260°	
"		~~Scissor~~ sisscors	4	FP		Pass	2:03p	260°	
3/24/17		specculums	13	FP		Pass	1:19p	260°	
"		IUC pack	1	FP		pass	1:19p	260°	
"		Sisscors	1	FP		pass	1:19p	260°	
3/24/17		Alligator forcep	1	FP		pass	1:19p	260°	

AUTOCLAVE LOG for Month March/April 2017

Clinic: Columbia

Biomedical company: BESS **Last Calibration Date:** APRN V list

Date of Monthly Infection Prevention Maintenance (Clean, drain & replace water): _____

Dates of weekly spore testing & results:

date of week 1_____ **pass / fail (circle one)**

date of week 2_____ **pass / fail (circle one)**

date of week 3_____ **pass / fail (circle one)**

date of week 4_____ **pass / fail (circle one)**

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials
3/31/17		IUC Pack	1	FP		Pass	9:54A	260°	
1		tenaculum	1	FP		Pass	9:54A	260°	
"		Specula ums		FP		pass	9:54A	260°	
4/6/17		IUC Pack	2	FP		pass	9:56A	260°	
"		Scissors	1	FP		P	9:56A	260°	
4/6/17		forceps Misquite	1	FP		P	9:56A	260°	
"		Specula ums	12	FP		P	9:56A	260°	
4/14/17		Ring forceps	4	FP		P	12:20	260°	
4/14/17		Misquite forceps	1	FP		P	12:20	260°	
4/14/17		IUC pack	1	FP		P	12:20	260°	
"		Specula ums	10	FP		P	12:20	260°	

HENRY SCHEIN®

135 Duryea Road, Melville, NY 11747
Questions: 1-800-472-4346

INVOICE

0100002214493406988141100000000002469404131174

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

SHIP TO/SOLD TO:
PP-Columbia Center MD
711 N Providence Rd
Orrin Moore
Columbia,MO 65203-4357

BILL TO:
Planned Parenthood Great Plains MD
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

BILL TO	SHIP TO	INVOICE AMOUNT
2214493	3329559	246.94

INVOICE#	INVOICE DATE
40698814	4/13/17

CUSTOMER PO#
COL-AB-04122017

ORDER#	ORDER DATE	DUE DATE
51118304	04/12/17	05/13/17

D&B#:01-243-0880
WHSE DEA# RH0162494 Fed ID: 11-3136595

LINE NO	ITEM CODE	UNIT SIZE	DESCRIPTION & STRENGTH	QUANTITY ORDERED	QUANTITY SHIPPED	ITEM STATUS	UNIT PRICE	EXTENSION	BOX NO	REM
			This order has been processed by our MIDWEST D.C. 5315 WEST 74TH STREET INDIANAPOLIS,IN 46268							
1	600-9638	1/BX	SOAKING CUP F/TRANSDUCER, ENDOCAV ** SPECIAL CONTRACT PRICE ** CASE GOOD ITEM, MAY BE SHIPPED SEPARATELY.	1	1	C T	96.04	96.04		
2	763-0012	EA	REVITAL-OX RESERT XL HLD 4LITER .GO TO YOUR ONLINE ACCOUNT TO RETRIEVE THIS MSDS/SDS, 105N508 - IF YOU CAN'T ACCESS ONLINE OPTIONS, CALL 1-800-472-4346. ** SPECIAL CONTRACT PRICE **	1	1	*T	41.68	41.68		
3	124-4695	120/CA	STRIP TEST RVTL-OX RESERT ** SPECIAL CONTRACT PRICE **	1	1	T	93.96	93.96		

INCLUDED IN THE BELOW FREIGHT CHARGE IS A FUEL/HANDLING SURCHARGE. FOR THE CURRENT TERMS OF SALE GOTO HTTP://WWW.HENRYSCHEIN.COM/US-EN/MEDICAL/LEGALTERMS.ASPX
PLEASE REFER TO BACK OF PAPERWORK FOR DISCLOSURES/TERMS OF SALE

PLEASE NOTE THAT LATE PAYMENTS ARE SUBJECT TO A 1.5 % MONTHLY FINANCE CHARGE

MERCHANDISE TOTAL	231.68
SALES TAX	[illegible]

BILL TO	SHIP TO	INVOICE#	INVOICE AMOUNT
2214493	3329559	40698814	246.94
ORDER#	ORDER DATE	INVOICE DATE	# OF BOXES
51118304	04/12/17	4/13/17	2
CUSTOMER PO#			PAGE#
COL-AB-04122017			1

ITEM STATUS KEY
B - Backordered; Item will follow
D - Discontinued; Item no longer available
F - Special offer
M - Manufacturer will ship Item directly to you
P - Prescription Drug; Return Authorization Required
R - Refrigerated Item; May be shipped separately
$ - Special Schein Pricing
T - Taxable Item
U - Temporarily unavailable; please reorder
* - Item has MSDS

REM KEY
S - Special Kit
N - No Charge

Continued on Next Page .....

HENRY SCHEIN®

135 Duryea Road, Melville, NY 11747
Questions: 1-800-472-4346

INVOICE

0100002214493406988141100000000002469404131174

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

SHIP TO/SOLD TO:
PP-Columbia Center MD
711 N Providence Rd
Orrin Moore
Columbia,MO 65203-4357

BILL TO:
Planned Parenthood Great Plains MD
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

BILL TO	SHIP TO	INVOICE AMOUNT
2214493	3329559	246.94

INVOICE#	INVOICE DATE
40698814	4/13/17

CUSTOMER PO#
COL-AB-04122017

Please detach here and mail the above with your payment

ORDER#	ORDER DATE	DUE DATE
51118304	04/12/17	05/13/17

D&B#:01-243-0880
WHSE DEA# RH0162494 Fed ID: 11-3136595

LINE NO	ITEM CODE	UNIT SIZE	DESCRIPTION & STRENGTH	QUANTITY ORDERED	QUANTITY SHIPPED	ITEM STATUS	UNIT PRICE	EXTENSION	BOX NO	REM
						FREIGHT	CHARGES	5.25		
						Invoice Date +	30 days	246.94		

Please remit payments only to the following address:
Henry Schein, Inc.
Dept CH 10241
Palatine, IL 60055-0241

BILL TO	SHIP TO	INVOICE#	INVOICE AMOUNT
2214493	3329559	40698814	246.94
ORDER#	ORDER DATE	INVOICE DATE	# OF BOXES
51118304	04/12/17	4/13/17	2
CUSTOMER PO#			PAGE#
COL-AB-04122017			2

ITEM STATUS KEY
B - Backordered; Item will follow
D - Discontinued; Item no longer available
F - Special offer
M - Manufacturer will ship Item directly to you
P - Prescription Drug; Return Authorization Required
R - Refrigerated Item; May be shipped separately
$ - Special Schein Pricing
T - Taxable Item
U - Temporarily unavailable; please reorder
* - Item has MSDS

REM KEY
C - No charge

Planned Parenthood®
Care. No matter what.

Planned Parenthood Great Plains

Policy: CLEANING THE ULTRASOUND PROBE AND CARE OF THE ULTRASOUND MACHINE

Originator: Kristin Metcalf-Wilson DNP, WHNP-BC

Approval Date: 04/01/2017

Policy:

Ultrasound machines constitute a significant resource investment for the agency. Although care must be taken with all aspects of the machine, the probes are especially delicate. Be sure to refer to the owner's manual/manufacturer's recommendations provided with the machine being used in the center.

The level of disinfection needed in between patients is determined by the route of scanning and the type of tissue contact. Transvaginal ultrasound constitutes endocavity scanning with mucous membrane contact and thus requires high level disinfection of the probe between patients. Although the use of probe covers may minimize probe contamination, the failure rate is surprisingly high and their use does not remove the need for high level disinfection. Abdominal scanning over intact skin poses little contamination risk, making a lower level of disinfection acceptable.

Process in the Clinics:

Starting the day

- Inspect all cords and probes for possible defects that may pose a safety hazard to the operator or patients.
- Ensure that any cords are tucked out of the way and uncoiled. Rolling over, stepping on or continuous tangling of the probe cords may damage the wires contained within the cords, causing imaging problems.
- Ensure proper supplies are available: ultrasound gel, non-latex sheaths and/or condoms for use with the vaginal probe, drape sheets, mild soap, cleaning agent(s) and soaking container, indicator strips and log for results, 2x4 labels, soft cloths, Resert XL HLD solution, and a timer.

General cleaning considerations

- All probes should be disconnected from the machine before they are cleaned to minimize safety hazards (i.e. shock to the operator, water damage to the machine).
- Although paper towels may be used to gently remove a soiled sheath, they should not routinely be used in any other part of the cleaning process. Paper towels are like sandpaper to the probe's delicate membrane surface.

- A soft cotton pile or microfiber cloth/towel should be used in any of the cleaning routines that follow. Although there are some disposable disinfecting wipes on the market, they do not provide the high level disinfection needed for the vaginal probe.
- A new cloth/towel is needed for every step in the process, so one should have access to at least three cloths per every scan. The microfiber towels (available at Costco or most automotive parts stores) can easily be cut into smaller squares (4 per towel) without fraying of the material.
- Launder cloths/towels according state guidelines and in a manner that maintains their softness. Towels that have lost their softness should be discarded as they may harm the probe membrane. Microfiber towels should not be exposed to fabric softener as it diminishes their absorptive abilities.

Resert XL HLD Solution for high level disinfection

Cleaning agents vary in the length of time needed to achieve high level disinfection, cost, and associated materials needed for the safe use of the cleaning agent. In an effort to provide high level disinfection in the least complicated manner and the shortest possible period of time, Resert is used to disinfect the probe.

Resert XL HLD is a ready to use, high level disinfecting solution. Unlike other high level disinfecting agents, it is virtually odorless, requiring no special ventilation, non-staining, and does not require special precautions (dilution or deactivation) for disposal.

Once poured into the soaking chamber, Resert XL HLD solution is good for up to 21 days of reuse provided that the minimum recommended concentration (MRC) of 1.5% is present, as verified by the approved indicator strips. A log of indicator results should be maintained.

The original open date should be recorded on the Resert XL HLD solution bottle using labels. The manufacturer's information indicates that the solution is good in the original container until the expiration date listed on the container. The soaking chamber should also have a center-applied label that lists the date the solution was poured into it, solution expiration date and the anticipated 21 day end of life date. At the start of every day, the solution must be tested with a Verify Chemical Monitoring Strip for Resert Solutions. Record the results of the test in the Resert Log. If the solution fails the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin. The solution should be covered at the end of every day. Please note that the color of the solution may change to light amber over time. This is not an indication of a problem as long as the MRC is verifiable.

Steris, maker of Resert XL HLD, suggests the following procedure for the using Verify Chemical Monitoring Strip for Resert Solutions:

- Ensure that the bottle of indicator strips is labeled with an open date. The strips expire 90 days from the open date or on the listed expiration date, whichever date comes first.
- Remove an indicator strip from the bottle. Dip the indicator pad into the soaking solution for 2 seconds, blot any excess by touching the edge of the pad to a paper towel, and then lay flat with the indicator pad facing up for 90 seconds, using a timer to monitor. Compare strip to color reference on the bottle.
- At the end of 90 seconds, read and record the result in the appropriate log. A "pass" is indicated by a color change from yellow to black. A "fail" is indicated by any blue or yellow remaining on the pad after 90 seconds.

- If the solution "fails" the test or 21 days have elapsed, the solution must be discarded, the container cleaned, new solution added and tested before any disinfection cycles may begin.
- Controls should be run upon opening any new bottle of indicator strips.
    - For the positive control, dispense approximately 30mL of Resert XL HLD solution from an unopened bottle into a clean container. Run three test strips as per usual routine. All three strips must "pass."
    - For the negative control, dispense 15mL of Resert XL HLD solution from an unopened bottle into a clean plastic bottle, add 15mL of tap water to the bottle, and gently mix. Run three test strips as per usual routine. All three test strips must "fail."
    - If all six strips result as expected, the new bottle of Verify Chemical Monitoring Strip for Resert Solution may be used until the listed expiration date, whichever comes first. Be sure to record the open and controls run date on the bottle itself and in the log.
- Check state and local disposal regulations. Any expired or "failing" solution may be disposed of by flushing down the drain with water. The original container should be triple rinsed with water before tossing. Consult the MSDS for first aid measures. The indicator strips contain dye that may stain once activated but otherwise require no special precautions.

Cleaning of the vaginal probe

- Begin the day by testing the soaking solution to ensure that the MRC is met and verify that it is within the 21 day reuse range. Document results in the appropriate log.
- After scanning, unplug the probe from the machine and set the connector (plug) in the holder on the mounting kit that houses the soaking cup.
- Remove the contaminated probe cover with a paper towel and discard. Rinse the probe under water to remove any excess gel.
- Gently and thoroughly clean the probe using mild dish soap and a soft cloth, then rinse with running water, and dry with a clean soft cloth. Drying is important because it prevents progressive dilution of the soaking solution.
- Gently immerse the probe in the Resert XL HLD solution for eight minutes, using a timer to verify appropriate time interval. The immersion should include the entire transducer shaft (up to the ring that divides the handle from the transducer shaft) but none of the handle. See diagram in the manufacturer's probe brochure. <u>The probe should not be left soaking any longer than the recommended eight minutes, as this may damage the probe covering.</u>
- Rinse well with running water and dry using a clean soft cloth.
- Plug the connector back into the machine. The probe is now ready for use with the next patient.
- Note the aforementioned cleaning regimen requires the use of three soft cloths/towels per each probe disinfection and at least five minutes to elapse on the timer before calling back a new patient.

Alternative Bleach Solution high level disinfectant

A dilute bleach soak should be created by mixing 10mL of chlorine bleach with one liter of tap water. Pour the solution into a tall soaking container with a wide bottom for stability and set the solution in the corner of the sink to minimize spillage. This is to be used only in the event that Resert XL HLD and/or Steris Monitoring Test Strips are not available for use. The dilute bleach solution needs to be remade on a daily basis. Before substituting dilute bleach solution for Resert, staff must notify the Ultrasound Program Director or Manager with the reason.

- Remove the contaminated probe cover with a paper towel and discard. Use a soft cloth to remove any excess gel from the probe.
- Unplug the probe from the machine, setting the connector (plug) carefully on a dry counter.

- Gently but thoroughly clean the probe using a mild dish soap and a soft cloth, then rinse with running water.
- Immerse the probe in the dilute bleach solution for two minutes. Note: the immersion should include the entire transducer shaft but none of the handle.
- Rinse well with running water and dry using a soft cloth.
- Plug the connector back into the machine. Probe is now ready for use with the next patient.
-

Cleaning of the abdominal probe

Abdominal probes should be cleaned and disinfected but do not generally require high level disinfection between patients.

- Remove any excess gel from the sides of the abdominal probe with a clean soft cloth. Spray probe with an ultrasound disinfectant detergent such as T-Spray and wipe thoroughly with a clean soft cloth.
- For this process, the abdominal probe does not need to be disconnected from the ultrasound machine.

Cleaning at the end of the day

Perform an extra cleaning of the probes at the end of the day to ensure equipment is left in optimal condition and ready to use. The Resert XL HLD solution should be covered. Launder any used cloths according to center and state guidelines.

Miscellaneous cleaning and service

Dust all areas of the machine twice per month or as needed with a lightly damp cloth. This is most easily accomplished with the machine turned off. The trackball may be removed and cleaned as need.
The screen may be cleaned using an alcohol swab and a soft cloth or Kimwipes. This task is best performed with the machine turned off and by working in quadrants so as to avoid streaking.

Annual maintenance of the machines may be provided by a manufacturer representative.

If trouble call service is needed, please contact agency resources to determine if the issue can be solved internally (IT or other staff) or requires a service call from the manufacturer. Contact a member of leadership to determine if service charges from the manufacturer are acceptable as the minimum trip charges are quite high.

Exporting files for storage

Files should be exported to CD/DVD or deleted from ultrasound machine hard drive storage before 50% of the hard drive capacity is exceeded. Failure to do so may result in sluggish performance of the machine.

Reference: ARMS Infection Prevention Manual

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Start a new log sheet when opening new solution or test strips.

Lot #: _____ Date opened: _____ Printed expiration date: _____

Lot #: _____ Date opened: _____ Initials: _____

Printed expiration date: _____ 180 day post-open date: _____ **Discard by earliest of these two dates*

Positive Control Solution (30 mL Resert XL Solution)

Positive Results: 1) Pass / Fail 2) Pass / Fail 3) Pass / Fail

Negative Control Solution (15 mL Resert XL Solution + 15 mL tap water)

Negative Results: 1) Pass / Fail 2) Pass / Fail 3) Pass / Fail

							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	
							Pass / Fail	

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RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

RESERT XL HLD SOLUTION

Printed expiration date: ______________
Date poured: ______________
End-of-life date (21 days post-pour): ______________

Discard by earliest of the two expiration dates.
Check MRC daily!

EXHIBIT 5

QUALITY ASSURANCE & RISK MANAGEMENT PLAN

Columbia Health Center
Comprehensive Health of Planned Parenthood Great Plains Inc.
711 N Providence Rd
Columbia

November 2016

Americans United for Life

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APPROVAL PAGE

COLUMBIA CLINIC
Comprehensive Health of Planned Parenthood Great Plains Inc.
711 N. Providence Rd.
Columbia, MO 65203

Clinic Risk Manager: Lead Nurse Practitioner

Quality Assurance & Risk Management Committee Members:
- Medical Director (Orrin Moore MD)
- Administrator (Vicki Casey)
- Vice President Health Center Operations (Amanda Addison)
- Director of Patient Care and Lead Clinician (Kristin Metcalf-Wilson)
- Staff physician / Consultant physician
- Director of Compliance and Quality Risk Management PPGP (Janet Smith)

This document is in accordance with the requirements of The Department of Health and Senior Services, Division of Regulation and Licensure. The following Risk Management Plan has been reviewed and is approved for use by the Chairman of the Board of Directors, President/CEO, Vice President of Health Services, and Risk Manager/Lead Nurse Practitioner.

Chairman of the Board of Directors	(see attached page) Date
President/CEO	5/15/17 Date
Administrator	5/15/17 Date
Risk Manager	5/15/17 Date

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Planned Parenthood®
Care. No matter what.

Comprehensive Health of
Planned Parenthood Great Plains

CORPORATE BOARD RESOLUTION

Risk Management Plan (Columbia, MO and Patty Brous Health Centers)

I HEREBY CERTIFY that at a meeting of the Board of Directors of **Comprehensive Health of Planned Parenthood of Great Plains, Inc. (CHPPGP)**, a corporation organized and existing under and by virtue of the laws of the State of Missouri, held on the 6th day of December, 2016, at which said meeting a quorum was present and acting throughout, the following resolution was adopted and ever since has been and now is in full force and effect.

RESOLVED, that the Board of Directors of CHPPGP hereby approves the Risk Management Plan of CHPPGP Columbia MO and Patty Brous Health Centers which meets all Kansas statutes and regulations

In witness whereof, I have hereunto set my hand this 6th day of December 2016.

Marjorie Sable

Marjorie Sable
Board Secretary

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1. PURPOSE

The quality assurance and risk management program of Columbia Center of Comprehensive Health of Planned Parenthood Great Plains is designed to assure the standard of care by the staff is maintained at an acceptable level to reduce the risk of patient injury and to minimize financial loss to the facility.

2. OBJECTIVES

The risk management program is designed to:

1. Identify areas of risk in the clinical aspects of patient care and safety.
2. Identify criteria for screening cases with risk potential regarding clinical aspects of patient care and safety.
3. Establish the investigative and evaluative process applied to cases with risk potential.
4. Assure timely intervention in events below the standard of practice.
5. Develop policies and programs to reduce risk in clinical aspects of patient care and safety.
6. Establish communication between risk management and quality assurance/improvement functions in the facility.

3. GOVERNING BODY AUTHORITY

The governing board hereby duly constitutes the Risk Management Committee and the Medical Staff Executive Committee as the committees responsible for investigating and determining applicable standards of care as required by Missouri CSR 30-30.050-060. These committees are established for the purposes of complying with risk management statutes; to evaluate and improve the quality of health care services provided in this facility. The governing board has the final responsibility and authority for the risk management program of Columbia Center of Comprehensive Health of Planned Parenthood Great Plains.

This plan was developed in accordance with provisions of the Missouri Code of State Regulations for abortion facilities. Responsibility for implementation of this plan is delegated to the Administrator. In the absence of the Administrator, the Director of Regional Health Services shall be in charge.

4. REPORTING OCCURRENCES/INCIDENTS/REVIEW OF APPROPRIATENESS OF CARE:

In accordance with CSR 30-30.060(1)(J) the quality assurance program includes all health and safety aspects of patient care and includes a review of appropriateness of care. Results of the quality assurance program are reviewed on a quarterly basis by the Administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following:

1. Completeness of clinical records
2. Incidence of morbidity and mortality
3. Intraoperative and postoperative complications (defined as including but not limited to, hemorrhage, infection, uterine perforation, cervical lacerations and retained products (19 CSR 30-30.050(1)(D))
4. All cases transferred to a hospital
5. All cased that resulted in a length of stay of more than twelve (12) hours
6. Errors in diagnosis
7. Problems in compliance with state and local laws and regulations
8. All cases in which the gestational age was determined to be beyond eighteen (18) weeks

Pursuant to RSMO 537.035, a "health care professional" is defined as a physician, surgeon, dentist, podiatrist, optometrist, pharmacist, chiropractor, psychologist, nurse, social worker, professional counselor, or a mental health professional while acting within their scope of practice.

"Risk Manager" means the individual designated by a medical care facility to administer its internal risk management program and to receive reports of reportable incidents within the facility.

When a reportable incident is identified, the person with knowledge of the incident enters it into the occurrence- reporting database for the risk management program. All reportable incidents are to be reported to the risk manager within 24 hours of discovery.

Identification of reportable incidents may be generated by, but not limited to the following methods:

- Personal Observation
- Occurrence Reports
- Infection Control Reports
- Complication Reports
- Death Reviews
- Tissue Reviews
- Patient Satisfaction Surveys
- Patient/Family Complaints
- Medical Record Reviews from all available services

Duly appointed ambulatory surgical center surveyors of the department shall be allowed to inspect the facility at any time the facility is in operation consistent with due regard for the medical condition and privacy of the on-site patients.

The risk manager shall have the authority to review all abortion facility and medical policies, procedures, records, committee minutes and actions, to make recommendations to CHPPGP administration and the medical staff and to initiate independent investigations.

5. INVESTIGATION OF OCCURRENCES

All clinical occurrence reports will be investigated by the risk manager or her/his designee and presented to the physicians' quarterly Quality / Peer Review Committee to determine whether the standard of care was met and to identify opportunities for improvement or education. The Quality / Peer Review minutes will reflect evidence of action taken as a result of the identification of the problems (CSR 30-30.060(1)(K)). All reviewers and committees shall be considered peer review committees pursuant to the provisions of CSR 537.035.

The Risk Management Committee functions as the clinic risk management committee. Members include the Medical Director, Administrator/Director of Regional Health Services, clinic Risk Manager/Director of Patient Care, Vice President of Health Center Operations, Staff Physician(s)/Consulting Physician, Director of Compliance and Quality Risk Management for PPGP.

With respect to each reported occurrence, the physicians' Quality / Peer Review Committee must determine: (1) whether individual health care providers met applicable standards of care expected in the abortion facility (2) if not, whether failure to meet those standards had a reasonable probability of causing injury to a patient; and (3) whether any action by a health care provider might be grounds for disciplinary proceedings by an appropriate licensing agency.

The activities of the Risk Management Committee shall be documented in its minutes at least quarterly.

The Risk Management committees may call upon the expertise of any abortion facility personnel or members of the medical staff in fulfilling their functions. All abortion facility personnel, administration, and members of the medical staff shall be obligated to cooperate with the Risk Management committees in acknowledgment of the joint responsibility of the medical staff, abortion facility personnel, and administration for risk management pursuant to Missouri law.

The Medical Director is responsible for notifying a physician when an adverse finding has been reported to their licensing agency; the Lead Clinician will notify nursing staff of an adverse finding and report to the Board of Nursing.

6. STANDARD OF CARE DETERMINATIONS
Columbia Clinic of Comprehensive Health of Planned Parenthood Great Plains will use the following categories: Standards of care met;

(1) Standards of care not met, but with no reasonable probability of causing injury;
(2) Standards of care not met, with injury occurring or reasonably probable; or
(3) Possible grounds for disciplinary action by the appropriate licensing agency.

*A finding of category 3 or 4 is an adverse finding and by law must be reported to the appropriate licensing agency.

"Reportable incident" means an act by a heath care provider which: (1) is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency.

8. MINIMIZING OCCURRENCES
Columbia Center of Comprehensive Health of Planned Parenthood Great Plains has established the following mechanisms to minimize occurrences:

1. Education: All new employees will receive information mandating their obligation to report reportable incidents to the risk manager. The purposes of risk management and how to report in this facility will also be explained. The Risk Management Plan will be reviewed at this time. Each employee will receive risk management in-service on an annual basis thereafter. A copy of the Risk Management Plan and a printed handout explaining the risk management law will be provided to each provider and each board member at the time of appointment and annually, thereafter. The plan will be reviewed and approved by the governing body annually. Any time the plan is amended, physicians and employees will be informed of the changes.

2. Credentialing. When, after an investigation, it is found that a reportable incident has occurred, a report will be made to the appropriate licensing agency in accordance with procedures identified in this policy. All risk management determinations will be considered in relationship to provider credentialing and the evaluation of employee performance, as appropriate.

3. Monitoring Frequency. Data relevant to reported variances/incidents will be compiled by the risk manager in statistical summary and will be presented quarterly to the Director of Compliance and Quality Risk Management to be used for identifying trends in practice and patient care. The Quality Management Committee shall analyze the frequency and causes of incidents and pursue measures to minimize recurrence through the active cooperation of clinic staff, medical staff and administration. Statistical data and summaries shall also be reported to the governing board at least quarterly.

*Data obtained for the purposes of risk management and quality assurance pursuant to CSR 30-30.060 shall be considered confidential information and not discoverable in a court of law.

4. Facility Actions. Internal facility actions may be taken as a result of investigation and data compilation and shall be in accordance with medical staff bylaws, agency policy, and governing board bylaws.

8. PLAN
A current copy of the Quality Assurance and Risk Management Plan shall be included in the employee policy manual and the bylaws of the governing board and medical staff. The plan will be reviewed annually. The Missouri Department of Health and Senior Services will be notified in writing of any change in the designation of the administrator of the facility.

9. CONFIDENTIALITY

Any person or committee performing any duty pursuant to this plan shall be designated as a peer review officer or committee pursuant to RSMO 537.035 and the amendments thereto.

All reports and records made pursuant to RSMO 537.035 and amendments thereto, shall be confidential and privileged. Such reports and records shall not be subject to discovery, subpoena or other means of legal compulsion for their release to any person or entity and shall not be admissible in any judicial or administrative action, for failure to provide appropriate care, other than a disciplinary proceeding by the appropriate state licensing agency.

Pursuant to RSMO 537.05, no person who was in attendance at any peer review committee proceeding shall be permitted or required to disclose any information acquired in connection with or in the course of such proceeding, or to disclose any opinion, recommendation, or evaluation of the committee or board, or any member thereof.

No abortion facility personnel, member of the medical staff or facility board member shall disclose information concerning reportable incidents except to their superiors, abortion facility administrator, the risk manager, the appropriate abortion facility and medical staff committee or the licensing agencies, unless authorized to do so by the risk manager.

10. INTERFERENCE WITH RISK MANAGEMENT PROCESS AND RETRIBUTION FOR REPORTING

Attempts by any employee of the facility or members of the medical staff to inhibit or prevent any other employee or medical staff member from reporting what they believe meets the definition of a reportable incident, shall not be tolerated, and will result in reprimand, suspension, or termination of any person who does so try to inhibit or prevent.

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QUALITY ASSURANCE PROGRAM REVIEW FOR THE CHPPGP COLUMBIA CLINIC

__ Quarter 20__

To be reviewed quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body.

MEDICAL ABORTION COMPLICATIONS FOR THE COLUMBIA CLINIC:

Total # of Medical Abortions =
Total # of Medical Abortion Complications =
Total % of MAB Complications =

Physician	Dr. McNicholas	Dr. Yeomans
Procedures (denominator)		
Failed MAB		
Infection		
Retained POC/blood clots & debris		
Hematometra		
Incomplete MAB		
Hospital Transfers from clinic		
Hospital Transfers from home		
Undiagnosed Ectopic		
Non-ectopic "errors" in diagnosis		
Hemorrhage/Heavy bleeding requiring tx		
Timely/Completeness of clinical records audit results:		
Death		
Total number of complications (numerator)		

SURGICAL ABORTION COMPLICATIONS FOR THE COLUMBIA CLINIC:

Total # of Surgical Abortions =
Total # of Surgical Abortion Complications =
Total % of Surgical Abortion Complications =

Physician	Dr. McNicholas	
Procedures (denominator)		
Failed surgical procedures		
Infection		
Retained POC/blood clots & debris		
Hematometra		
Perforation/laceration		
Hospital Transfers from clinic		
Hospital Transfers from home		
Undiagnosed Ectopic		
Non-ectopic "errors" in diagnosis		
Hemorrhage/Heavy bleeding requiring tx		
Timely/Completeness of clinical records audit results:		
Death		
Total number of complications (numerator)		

PROBLEMS WITH COMPLIANCE WITH STATE AND LOCAL LAWS AND REGULATIONS REGARDING ABORTION:

GOOD CATCHES:

Risk Management Review Date _____

Members Signatures present:

_____ Medical Director

_____ Staff Physician

_____ Staff or Consulting Physician

_____ Administrator

_____ Director of Patient Care

_____ Director of Compliance & Quality Risk

Date of quarterly Review by PPGP Board of Directors: _____

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EXHIBIT 6

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HENRY SCHEIN®

135 DURYEA ROAD
MELVILLE, NY 11747

SHIP TO:

PP-Columbia Center
711 N Providence Rd
Orrin Moore
Columbia MO 652034357

BILL TO:

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park KS 662111303

Order Confirmation

Planned Parenthood Great Plains
4401 W 109Th St Ste 200
Overland Park, KS 66211-1303

ACCOUNT #	TOTAL AMOUNT
2214493	95.21
ORDER NUMBER	ORDER DATE
52037758 SE	05/11/17
PAGE #	...
1	

LINE NO	ITEM CODE	UNIT SIZE DRUG CLASS	DESCRIPTION & STRENGTH	QTY. ORD SHIPPED	SHIPPING DETAILS CUSTOMER P.O.#	UNIT PRICE	EXTENSION
1	9879426	100/Bx PU	Needle Disposable 21gx2" 05/11/17 1.000	1 1	SHIPPING COL-AB-05112017	15.74	31.48
2	2170030	Ea PU	Formalin 10% NBF 1 Gal 05/11/17 2.000	2 2	SHIPPING COL-AB-05112017	28.12	56.24
3	1089349	Ea	Hand Pump f/Hibiclens Gallon 05/11/17 1.000	1 1	SHIPPING COL-AB-05112017	1.88	1.88
4			SHIPPING AND/OR HANDLING			1.75	1.75
5			TAX			3.86	3.86

Included in the below freight charge is a fuel/handling surcharge. For the current terms of sale goto http://www.henryschein.com/us-en/MEDICAL/legalTerms.aspx

ACCOUNT #	TOTAL AMOUNT
2214493	95.21
ORDER NUMBER	ORDER DATE
52037758 SE	05/11/17
PAGE #	...
1	

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EXHIBIT 7

ING SLIP

DATE: 04/21/2017

85092812BP04654612

McKESSON

TO: 56799187	BILL TO: 54565244	FROM:
NNED PARENTHOOH GREAT PLAINS 1 N PROVIDENCE RD COLUMBIA, MO 65203	PLANNED PARENTHOOD 4401 W109TH ST STE 200 OVERLAND PARK, KS 66211	MCKESSON MEDICAL-SURGICAL INC(KANSAS CTY KANSAS CITY PC # 003 1405 N. CHOUTEAU KANSAS CITY, MO 64120 AB
CUST P.O. NUMBER: COL-AB-04202017-1 ORDERED BY: EJJ7ED0	INVOICE NUMBER: 1836809 **ORDER NUMBER: 85092812 SO** ORDER DATE: 4/20/2017	DISTRICT 2001031644 LICENSE:
FOB Destination	Regulatory License: 2004030009	

LN #	Item / Mfg Number	Qty Ordered	UOM Bin Loc	Shipped	To Follow	Description Vendor	Cust Item #
2	848309 & 00562780505	2	BX	2	✓	RHOGAM, SYR PLUS ULTR FILTERED 300MCG (5/BX) KNDBIO	/IBX848309

For Drug Supply Chain Security Act (DSCSA) inquiries, please log on to McKesson SupplyManager℠, then select "DSCSA Traceability Reporting" under the "Reports" tab. For questions, email DSCSARegulatory@McKesson.com. McKesson's Terms of Sale shall apply to all purchases. Any discrepancy between any order placed under this Agreement and McKesson's corresponding shipment must be reported to McKesson for resolution within ten (10) Calendar days of McKesson's invoice date except for price or payment discrepancies which shall be reported to McKesson for resolution within thirty (30) days of McKesson's invoice date. Prices exclude taxes and service fees. Failure to report within the designated time shall constitute a waiver of any claims due to such discrepancy.

Contact your Customer Service Center if Safety Data Sheets are needed.

Rx Package insert information can be found at the website, http:DAILYMED.NLM.NIH.gov/dailymed/about.cfm. If you have trouble accessing the website and need package insert information, please contact Customer Service and request a copy.

NOTE - '*' Next to Line Number Indicates Shipping from Another Location
'**' Next to Line Number Indicates Line Under Review

(CONTINUED NEXT PAGE)

TA 4-26-17

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EXHIBIT 8

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Medical AB SUPPLY LIST

Craig Medical
Eldon Cards DKS RhD-25

Immucor – 1-800-829-2553
Eldon Card Control
Panoscreen III Item #0002381

Henry Schein
HemoCue Controls (Low/High)
HemoCue Microcuvettes
Lancets 21 G Safety
Digital Ear Thermometer
Thermometer Covers
Ultrasound Gel
Ultrasound Probe Covers
Sani-Cloth Disinfectant Wipes
Non Latex Condoms
PTU's
Paper Bags
Drapes
Urine Cups
Drinking Cups
Urine Dip Sticks

PDRX
Zithromax – 500 mg
Ondansetron 4 mg
Tylenol 3 – 30 mg
Cytotec (Misoprostol) 200 mcg tablets
Rhogam (1/2 dose)

Smith Medical
Mifeprex – 200mg

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First Trimester Surgical AB List

Ibuprofen 800 mg

Azithromycin 500 mg

Emergency medications/Crash cart – see Arms Emergency Procedure Guide

Valium 10mg I pill by mouth-given before procedure

Methergine-0.2mg/ml

Lidocaine HCl- 1% - 10ml syringes

22G Spinal Needle

Non sterile 4 x 4 gauze pads

Lubricating jelly packets

Hibiclens

Flexible Cannulas Size 6-12

Rigid Cannulas Size 6-14

Suction tubing

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Columbia HC

Pharmaceuticals	Count	Expiration Date	Pharmaceuticals	Count	Expiration Date
Crash Cart			**Medications:**		
Month/Year May 2017			*Ammonia Capsules (6)	10	6/19
SUPPLIES:			Atropine Sulfate 0.4 mg/ml	1	4/18
*O2 tank	Full		Diazepam 10 mg	100	6/17
*3cc syringes with 21g/22g needles	9	N/A	Diazepam 5 mg/ml vial	10	9/17
*Adult Bag Valve Mask and Tubing	1	N/A	*Diphenhydramine Hydrochloride (Benadryl) 25 mg po x 6	100	12/17
AED On Cart w/ Adult Pads	✓		*Diphrenhydramine Hydrochloride (Benadryl) 50mg/ml (1ml vial x 4)	4	10/18
*Alcohol Preps	12	N/A	*Epi-pen	1	8/17
*Angiocaths – 18, 20, ~~22~~	6	4- 9/19 2 - 4/19	*Epinephrine 1:1000 Ampoules x 4	4	8/17
Endotrachial tubes	6	5.0 = 7/19 ~~8.0~~ = 5/20 7.5 = 3/20	*Flumazenil 5ml vial 0.1 mg/ml	10	10/18
*Exam Gloves (non latex)	✓	NA	Lidocaine HCL 1%	1	2/2018
*IV bag – normal saline	2	10/17	*Methylergonovine 0.2 mg/ml vial	10 In Recovery fridge	6/2018
*IV bag - Ringers Lactate	4	11/18	*Misoprostol 200 mcg	8 tabs	~~5/17~~ 5/18
*IV tubing	2	12/19	*Naloxone vial 0.4mg/ml	1	11/17
IV start Kit N/A			*Oxytocin 10 units/ml	2	1/18

Laryngoscope	1	N/A	Solumedrol	1	8/20
*one-way valve mask			*Vasopressin 20 units/ml vial	25	7/18
*Oral Airway Set	1	N/A			
*nasal cannula	1	N/A			
*Non rebreather Face Mask	1	N/A			
*Sterile 4x4 gauze	2	N/A			
Scissors	1	N/A			
Tourniquet	1	N/A			
*Tape Plastic/Paper					
*TB syringes	5	N/A			
			Nurse:		

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Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

August 11, 2017

Amanda Addison (Amanda.addison@ppgreatplains.org)
Comprehensive Health of Planned Parenthood Great Plains
711 North Providence Road
Columbia, Mo 65203

Re: Comprehensive Health of Planned Parenthood Great Plains – Columbia Revisit Survey

Dear Ms. Addison:

The Department received the application for licensure of the Columbia Planned Parenthood location as an abortion facility. Department staff conducted an onsite survey of the facility on October 11, 2016 to determine compliance with the terms of the 2010 settlement agreement and applicable statutes and regulations. As a result, on November 2, 2016, your facility was provided with a list of regulatory items that were not in compliance.

After the facility submitted a complete response and documentation regarding correction of the items that were not in compliance, the Department performed an onsite revisit of the facility on July 25, 2017.

Listed below are items the revisit survey indicated were still not in compliance. Until a written response is provided describing how all items below have been addressed, including acceptable evidence of compliance, an abortion facility license cannot be issued.

19 CSR 30-30.0601(B)8. The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment.

The facility failed to demonstrate compliance with facility's established Infection Prevention Program, based on Association for the Advancement of Medical Instrumentation (AAMI) and Centers for Disease Control (CDC) standards. Specific findings:

1. The facility failed to follow the manufacturer's instructions for use (IFU) for routine care of the sterilizers.

(AAMI 9.4 Routine Care: Sterilizers should be inspected and cleaned daily according to the manufacturers' written instructions. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturers' written IFU.)

2. The facility failed to maintain a separate autoclave log with the required components tracked for each of two sterilizers.

(AAMI 10.3.2 Sterilizer records: For each sterilization cycle, the following information should be recorded and maintained: Lot number; Specific contents of the lot or load, including quantity, department, and a specific description of the items [e.g. towels, type/name of instrument sets]; Exposure time and temperature, if not provided on the sterilizer recording chart; Name or initials of the operator; Results of biological testing, if applicable; Any reports of inconclusive or nonresponsive chemical indicators found later in the load.)

3. The facility failed to maintain a record of sterilizer maintenance and repair.

(AAMI 9.7 A maintenance record, in either paper or electronic format, should be kept for each sterilizer. At least the following information should be recorded:

a) The date on which service was requested;
b) The model and serial number of the sterilizer;
c) The location of the equipment (if applicable);
d) The name of the individual from the facility who requested and authorized the service;
e) The reason for the service request;
f) A description of the service performed ;
g) The types an quantities of parts replaced;
h) The name of the person who performed the service;
i) The date the work was completed;
j) The handwritten or electronic signature and title of the person who acknowledged completion of the work; and
k) The results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service.)

4. The facility failed to have written processes for reprocessing and/or quarantine of instruments following positive biological indicators, as well as consecutive biological testing following sterilizer failure and repair.

5. During an interview with facility advanced practice nursing staff at the time of the revisit, staff acknowledged the problems with adequate documentation and clear adherence to the AAMI standards.

Please respond in writing providing evidence/documentation that each of these items has been fully addressed and corrected.

If you have further questions, you may contact our office at 573-751-6083 or via email at the address noted below.

Sincerely,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Planned Parenthood®
Care. No matter what.

Comprehensive Health
4401 W. 109th St Suite 100
Overland Park, KS 66211
p: 913.345.1400 f: 913.345.2820
www.PPGreatPlains.org

Comprehensive Health of
Planned Parenthood Great Plains

August 16, 2017

John Langston
Bureau of Ambulatory Care
MO Department of Health & Senior Services
POB 570
Jefferson City MO 65102

Dear Mr Langston:

Please find attached our responses to the items regarding our infection prevention program that are needed to bring us into compliance.

1. Exhibit A
   Autoclave Policy referencing the requirement to follow the manufacturer's instructions for routine care of the autoclave. The policy includes cleaning instructions for the autoclave.

2. Exhibit B
   Updated "Autoclave Log". The second autoclave that was put into service while waiting for the repair of the first autoclave, has been taken out of the clean room and put in storage. If the second autoclave needs to be put in service, a new and separate autoclave log will be implemented.

3. Exhibit C
   - "Procedure to Respond to Autoclave Malfunction/Positive Spore Test/Maintenance checklist has been implemented that includes all information that is required to be documented after an autoclave fail or maintenance has been performed.
   - Maintenance record of autoclave repair done on 06/20/17.

4. Exhibit D
   "Autoclave Policy and Procedure for Autoclave Maintenance/Positive Spore Test" addresses reprocessing and/ or quarantine of instruments following a positive spore test, as well as consecutive spore testing requirements following a failure.

5. Exhibit E
   Staff Education/Reeducation Form
   Columbia health center staff have been educated regarding new autoclave and autoclave failure policies.

Please let me know if you need anything further.

Sincerely,

Amanda Addison
Vice President of Health Services
Planned Parenthood Great Plains
Amanda.addison@ppgreatplains.org
PH: 913-345-4659

Americans United for Life

EXHIBIT A

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Policy: Inspecting and Cleaning the Inside of the Autoclave

Originator: Health Services

Approval Date: July 2017

Policy:

1. Clinic staff will follow the autoclave policies and procedures described in the ARMS Infection Prevention Manual. The policies described here provide additional clarity on how to clean the autoclave.
2. It is the policy of PPGP to inspect and clean the autoclave by following the manufacturer's instructions. Each autoclave should have the manufacturer's instructions posted next to it.
3. Record the manufacturer's inspection and cleaning instructions in the autoclave log notebook.
4. The autoclave must be inspected and cleaned at the end of each day in order to remove any residue that settles onto the surface. Rationale: If the autoclave is not cleaned daily, residue may build up and become aerosolized in the steam, compromising the sterilization process.
5. The autoclave must be inspected and cleaned at least weekly with detergent or as recommended by the manufacturer.
6. The water in the autoclave must be changed at least monthly or as recommended by the manufacturer.
7. Each time the autoclave is cleaned (daily, weekly and as needed), document the cleaning or water change in the autoclave log. Record the brand of detergent that is used.

Reference:

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/sterilizing-practices.html

Comprehensive health of Planned Parenthood Great Plains
Policy on Cleaning the Autoclave

The inside of the autoclave must be wiped down at the end of each day in order to remove any residue that collects inside the chamber and around the door opening.

The autoclave must be cleaned at least once a week with Pelton's Original Formula Omni-Cleaner ("detergent") and distilled or demineralized water.

Clean the outside of the autoclave with water and a non-chlorinated detergent. Do not use chlorine, steel brushes, stainless steel, or steel wool. Always rub in the direction of the metal grain pattern. If the surface is contaminated, clean with a 5% solution of warm, oxalic acid.

When cleaning saline solutions, it is imperative that the autoclave be cleaned after each use (in order to get salt residue out of the autoclave before the salt can corrode the stainless steel finish).

- Mix 12 ounces of detergent in 1 gallon of water.
- Drain water from the autoclave reservoir.
- Refill reservoir with detergent solution.
- Run one, 20 minute sterilizing cycle. Do not sterilize instruments while cleaning autoclave.
- Drain cleaning solution from reservoir and chamber.
- Rinse thoroughly with clean, mineral-free water.
- Run a rinse cycle for 15 minutes.
- Drain rinse solution.
- Wipe inside of boiler thoroughly.
- If there are lime deposits inside the chamber, make sure the chamber is cool and clean with water, plastic or nylon scouring pads, and non-chlorinated detergent.
- Refill reservoir with clean, mineral-free water.
- The autoclave is now ready for use.

EXHIBIT B

Americans United for Life

AUTOCLAVE LOG for Month _____

Clinic: _____

Biomedical company: _____ **Last Calibration Date:** _____

Date of Weekly Cleaning & Water Change: _____

Daily inspection & wipe inside and door opening:

Week 1/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 2/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 3/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 4/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat
Week 5/initials:	**Mon**	Tues	Wed	Thurs	Fri	Sat

Dates of weekly spore testing & results reviewed by health center manager: **(an inconclusive or nonresponsive result counts as a failure*)**

date of week 1_____ **pass / fail (circle one)**

date of week 2_____ **pass / fail (circle one)**

date of week 3 _____ **pass / fail (circle one)**

date of week 4_____ **pass / fail (circle one)**

date of week 5_____ **pass / fail (circle one)**

*if test fails, see "responding to autoclave malfunction" checklist in Lab Manual

recommendations from AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006)

Date	Lot #	Contents description	quantity	FP/AB	Indicator	Pass/Fail	time	temp	initials

Americans United for Life

EXHIBIT C

Check if done	Procedure to Respond to Autoclave Malfunction/ Positive Spore Test or when maintenance is needed	date	time
	If the clinic is notified of a positive biological indicator (ie failed spore test), or if or if maintenance is needed, remove the autoclave from service. Put a sign on the autoclave telling staff not to use it and the reason why. Date and time the sign. Immediately notify the health center manager. If there was a positive spore test, make sure all items that were sterilized since the last satisfactory spore test remain quarantined. Borrow sterile items from another clinic if necessary. (Autoclave does not need to be removed from service if biomed is performing the routine yearly inspection and maintenance).		
	Make an entry in the autoclave log that the autoclave is out of service and no items are being sterilized in it.		
	Date when biomed service was requested:		
	Model & serial number of sterilizer:		
	Location of sterilizer:		
	Name of clinic staff who requested and authorized service:		
	Reason for service request:		
	Name of bio med service called & name of person spoken with:		
	If the clinic borrows a back-up autoclave to sterilize instruments, it must pass 3 spore tests before being used to sterilize items. The second autoclave must have its own autoclave log. If an autoclave was borrowed: Date: Model & serial number:		
	Name of biomedical tech who serviced the autoclave:		
	Date and time of service:		
	Description of service performed:		
	Types and quantities of parts replaced:		
	Date work was completed:		
	Attach the handwritten or electronic signature and title of the clinic staff who acknowledged completion of the work		
	Document the results of any post-test maintenance testing performed, if		

	needed, before the sterilizer was returned to service, including:		
	After the biomedical tech clears the autoclave to return to service, run 3 consecutive spore tests. For pre-vacuum autoclaves, also run 3 Bowie-Dickie tests. On the autoclave log, record the date and times the tests were run and mailed in.		
	Do not use the autoclave until all tests are satisfactory. Put a sign on the autoclave telling staff not to use it until the spore tests come back satisfactory. Make sure the health center manager and all staff are aware. Alternative: Quarantine sterilized items until the 3 spore tests come back satisfactory and are reviewed by the health center manager.		
	When the 3 spore tests are returned, are satisfactory, and are reviewed by the health center manager, the autoclave may be used to sterilize items. Date autoclave put back in service: Health Center Manager signs here to attest the 3 satisfactory spore tests were reviewed.		
	Comments:		

This check list also located in the Lab Manual (Chapter 3: Quality Assurance).

Reference:

ARMS Infection Prevention Manual

https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/sterilizing-practices.html

Association for the Advancement of Medical Instrumentation (AAMI) standards

Note: Missouri licensing survey team requires adherence to AAMI standards

Invoice

BESS Inc.
4203 East 109th Street
Kansas City, MO 64137
913 696-9977 fax 913 696-9981

Date	Invoice #
6/20/2017	8204

Bill To:

Planned Parenthood of Great Plains
4401 W 109th St, suite 200
Overland Park, KS 66211

Service To

711 North Providence Rd
Columbia, MO 65203

P.O. No.	Terms	Project
	Net 30	

Quantity	Description	Rate	Amount
	Pelton Crane Magnaclave Model MC Serial Number A6-5641 Overheating issues Disassembled and cleaned obstructed valve, reassembled and tested complete cycle, passed test		
1.5	Labor - Consultation	75.00	112.50T
4	Travel Time	60.00	240.00
	Tax Exempt - Certificate on file	0.00%	0.00

GP-84000 - HCFP-COL

RECEIVED JUN 21 2017

Total $352.50

Americans United for Life

EXHIBIT D

Planned Parenthood®
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Planned Parenthood Great Plains

Policy: Autoclave Policy and Procedure for Autoclave Maintenance/ Positive Spore Test

Originator: Health Services

Approval Date: July 2017

Policy: Planned Parenthood Great Plains (PPGP) clinic staff will follow the autoclave policies and procedures described in the ARMS Infection Prevention Manual.

It is PPGP's policy to run a spore test in each autoclave once a week. All items sterilized in the autoclave will be quarantined until the spore test comes back satisfactory. (Example: the spore test is conducted on May 1 and the test results are received at 8:00 am May 3. All instruments sterilized between May 1 and 7:59 May 3 are quarantined until the satisfactory spore test is reviewed). Rationale: Items must not reach patient until the test result confirms the autoclave killed all the spores in the test kit.

This policy and procedure describes what to do when staff have reason to believe the autoclave has failed, either by receiving a positive biological (unsatisfactory spore test) or by suspecting a mechanical malfunction (e.g. noticing a burning odor). This policy and procedure also describes the process that must be followed for autoclave maintenance.

Process in the Clinics:
When the autoclave is first installed and any time it is redesigned, after a repair, and after a sterilization failure has occurred, staff must run 3 satisfactory spore tests to ensure it is functioning prior to sterilizing items. The autoclave must be tested after it is relocated or there is a water line break with an autoclave that utilizes city water (Comp Health Overland Park autoclave).

When three consecutive spore tests come back satisfactory the autoclave can be used to sterilize items. Any items processed during the three evaluation cycles should be quarantined until the test results are satisfactory.

Spore tests, chemical tests, Bowie-Dickie tests and autoclave print-outs should be kept in the autoclave log for two (2) years.

July 2018

EXHIBIT E

STAFF EDUCATION/REEDUCATION FORM

Clinic: Columbia **Date:** 8/15/2017

Education/Reeducation Topic: Autoclave

Criteria presented:
- IP manual changes
- Autoclave Policy
- Autoclave log

Staff in attendance (please sign name):

Identified areas of concern (if any):

Corrective Action Plan (how will staff be monitored):
- HCM/or NP will monthly check log, and weekly check to ensure sterilization strips are sent
- NP will ensure spore testing is Pass, and will follow protocol if there is a fail.

Clinician signature:

Clinic manager signature:

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

October 3, 2017

Vicki Casey
Comprehensive Health of Planned Parenthood Great Plains, Inc.
711 North Providence Road
Columbia, MO 65203

Re: Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia survey

Dear Ms. Casey:

Please see attached results of the recent follow-up survey of August 28, 2017. Your facility is now in compliance with current legal requirements for licensure.

Please retain this material for your own records. The abortion facility license is attached, effective date October 3, 2017.

We welcome any questions at 573-751-6083.

Respectfully,

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 08/28/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH PLANNED PAREN	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An onsite Licensure revisit survey was conducted on 08/28/17. The facility was found to be in substantial compliance with the rules and regulations for abortion facilities found at 19 CSR 30-30.060.	{L 000}		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	10/11/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PARENTHC	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Initial Comments A full licensure survey was conducted at the facility on 10/11/16 to determine compliance with state requirements for Abortion Providers, which includes state rules 19 CSR 30-30.050-30.070, applicable portions of Chapter 197 and 188, as well as the 2010 settlement agreement between DHSS and the facility. The survey was conducted prior to issuing a license for the facility to resume providing abortion services at this location. A Statement of Deficiencies (SOD) in the form of a findings letter was sent to the facility instead of a Form 2567 in early November 2016. Following receipt of this findings letter, in early December 2016, the facility filed suit against DHSS in federal court (Case No. 2:16-cv-04313-HFS), primarily regarding DHSS ' s ongoing enforcement of Missouri requirements for ASC standards and physician privileges, following the SCOTUS decision in Whole Woman ' s Health v. Hellerstedt. As of 1/6/17, no formal response to the SOD has been received, no license has been issued. This survey process will be suspended/closed, and no further licensure activity planned pending the outcome of the federal case. This entry is being made for record-keeping and historical purposes, and should not be considered part of the formal SOD. Addendum: October 2017: After multiple court proceedings, DHSS did receive an SOD and conducted sufficient follow up activities to ensure that all requirements were eventually determined to be met. The Columbia location was eventually granted an Abortion Facility license effective date 10/3/2017.	L 000		

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	10/11/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PARENTHC	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L 000	Continued From page 1 Survey process closed. BAC Admin.	L 000		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired: 1-800-735-2466 VOICE: 1-866-735-2460

Randall W. Williams, MD, FACOG
Director

Eric R. Greitens
Governor

December 18, 2017

Diana O. Salgado
Senior Staff Attorney
Public Policy Litigation and Law
Planned Parenthood Federation of America

Via email to Diana.Salgado@ppfa.org

Re: Proposed complication plan for Columbia, Missouri abortion facility

Dear Ms. Salgado:

The proposed complication plan submitted by Comprehensive Health of Planned Parenthood Great Plains regarding the Columbia facility ("facility") on November 14, 2017, does not meet the requirements of section 188.021, RSMo, and 19 CSR 30-30.061 in that:

1. The complication plan does not include the telephone number(s) or address of the OB/GYN or OB/GYN group providing complication care. Patients are only given the number of the facility's on-call nurse;
2. The complication plan does not provide for continuity of patient care in that when Dr. McNicholas is not available, Dr. Orrin Moore, the back-up physician listed in the complication plan, is located in Overland Park, Kansas, which is approximately 125 miles from Columbia, Missouri, where the facility is located. According to the complication plan, patients needing follow-up care when Dr. McNicholas is not available are to receive that care from Dr. Moore at a PPGP health center in Overland Park or go to Boone Hospital Center in Columbia to be seen by Boone Hospital Center's on-call physician. Otherwise, the patient is to be directed to go to the nearest emergency room. It is our understanding that Dr. McNicholas is principally located in St. Louis, Missouri, and is only occasionally in Columbia; and
3. The complication plan fails to recognize the importance of the physician-patient relationship by providing for continuity of care and ensuring communication among the physician who induced the abortion and all subsequent health care providers involved in treating the patient's complication.

Because the facility's proposed plan does not meet the requirements of Section 188.021, RSMo, and 19 CSR 30-30.061, the Department cannot approve the plan. Accordingly, no drugs or chemicals for which the federal Food and Drug Administration label includes any clinical study in which more than one percent (1%) of those administered the drug required surgical intervention after its administration may be prescribed or administered via the facility until a new or revised complication plan has been submitted to and approved by the Department in writing.

If the facility wishes to submit a new or revised plan, please send it to the Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102, or by email to John.Langston@health.mo.gov by January 15, 2018.

Sincerely,

John Langston
Administrator
Bureau of Ambulatory Care

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

June 18, 2018

Brandon J. Hill, PhD
President and CEO
Comprehensive Health of Planned Parenthood Great Plains (re: Columbia Clinic, A004)
4402 W 109th Street, #100
Overland Park KS 66211

Dear Dr. Hill:

This is in response to your letter requesting a waiver of the regulatory requirement for a pelvic exam prior to a medical abortion (19 CSR 30-30.060(2)(D)), *specifically for the Columbia, Missouri location (A004).* The department has considered the request and determined that the requirement is proper. Additionally, there is no provision in the abortion facility regulations that authorizes the department to grant waivers of this requirement. The 2010 settlement agreement between DHSS and Planned Parenthood exempts only the Kansas City location from this requirement. Therefore, the request is denied.

Sincerely,

John Langston

John Langston, Administrator
John.Langston@health.mo.gov
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

Americans United for Life

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Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

June 14, 2018

Dr. Randall Williams
Missouri Department of Health and Senior Services
912 Wildwood
Jefferson City, MO 65102-0570

Via U.S. Mail and electronic mail to randall.williams@health.mo.gov

Dear Dr. Williams:

It has come to our attention that the Department of Health and Senior Services (DHSS) has begun to require all abortion patients to submit to a pelvic exam prior to having an abortion, including a medication abortion. On behalf of Comprehensive Health of Planned Parenthood Great Plains (Comprehensive Health), which operates licensed abortion facilities in Kansas City and Columbia, we are applying for a waiver of the state mandated pelvic exam requirement, 19 CSR 30-30.060(2)(D), prior to medication abortions. As the Department is aware, it has already waived the requirement as to our Kansas City facility; therefore, our request seeks to extend the waiver to our Columbia facility.

The health and safety of women is our mandate. The most recognized national medical experts on women's health and abortion – the American College of Obstetrics and Gynecology (ACOG), Planned Parenthood Federation of America, and the National Abortion Federation – consider a pelvic exam prior to a medication abortion medically unnecessary except in very specific circumstances. These experts have established the standards of all American gynecologic care based on an expansive review of care provided across a variety of settings, circumstances, and involving millions of patients. In addition, recently the National Academies of Sciences, Engineering and Medicine published a comprehensive report on the safety and quality of abortion care in the United States, which confirmed that the clinical assessments required prior to medication abortion do not include a pelvic exam for all women.

The State of Missouri, in dictating the policy of a pelvic exam prior to medication abortion for every patient, regardless of her individual, medical and personal history, is mandating a requirement that goes against an evidence-based approach to medical care for women, potentially violates ethical and medical consent practices, and forces women to submit to an intrusive examination that is not necessary to ensure their health and safety. Our physician at our Columbia health center does not believe she can ethically require women to undergo a pelvic exam prior to medication abortion, unless such an examination is medically indicated based on patient-specified issues.

Further, as our society grapples with the many concerns raised by the "Me Too" movement and alarming increased instances of assaults perpetrated under the guise of "medical care", including those committed by Dr. Larry Nassar and University of Southern California physician

Dr. George Tyndall whose behavior during pelvic exams was deemed outside the scope of current medical practices, we believe it is imperative that state officials be committed more than ever to the protection of women's bodily integrity. Our commitment is unwavering, and we are hopeful that the Department will be reasonable in its interpretation of this requirement.

The Department has historically elected not to enforce this requirement for medication abortion procedures, making clear that it is unnecessary for the health and safety of women. In prior annual inspections by the Department, we have never been issued a citation on this issue by state surveyors. Indeed, email communications between state surveyors indicate they accepted that pelvic examinations were unnecessary because sonograms are performed for every patient. In addition, as stated above, our Kansas City health center is exempted from performing pelvic exams prior to a medication abortion when such an exam is not medically indicated. Moreover, any hospital that provides a medication abortion to a woman does not need to abide by this requirement as it is a standard specific only to abortion facilities. Thus, there is no basis to conclude that the pelvic examination requirement is necessary for women's health. On the contrary, the requirement only serves to place an additional, offensive burden on abortion access in Missouri.

Losing the option of medication abortion in Missouri will negatively impact the health and safety of women by forcing patients to consider surgical options despite reasons to prefer medication procedures, postpone their procedures to later gestational ages, or not access abortion care at all. As the Department recognized in the emergency complication-plan regulation, medication abortion may be medically appropriate over surgical abortion for some women.

I implore you to grant Comprehensive Health a waiver from the pelvic exam requirement for women choosing medication abortion. Thank you for your attention to this critical health matter. I am also available at any time for a discussion of this important matter. In addition to this letter, please consider the supporting documentation attached to Reproductive Health Services of Planned Parenthood of the St. Louis Region's similar request for a waiver.

Sincerely,

Brandon J. Hill, PhD
President & CEO
Comprehensive Health of Planned Parenthood Great Plains

cc: John Langston, Bureau of Ambulatory Care, DHSS
Amanda Addison, Vice President for Health Services, Comprehensive Health

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 30, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains
711 N Providence Road
Columbia, MO 65203

RE: ***Licensure Survey TKOR11***

Dear Vicki Casey:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***August 14, 2018*** in connection with the ***State Licensure*** requirements as they pertain to abortion centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Enclosure

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 08/13/18 to 08/14/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L1081	19 CSR 30-30.060(1)(B)(3) The administrator shall be responsible, plan The administrator shall be responsible for developing a written plan for evacuation of patients and personnel in the event of fire, explosion, active shooter, or other disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. Disaster drills with participation of all staff shall be conducted and documented at least annually. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that all staff participated in drills and were knowledgeable about the plan. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's document titled, "Quarterly Fire Drill Report," dated 02/18/18, showed that the facility had a fire drill on that date. The previous fire drill was held on 04/05/17. 2. During an interview on 08/14/18 at 2:33 PM,	L1081		

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L1081	Continued From page 1 Staff C, Health Center Manager, stated that: - She had been employed at the facility since March. - She had not participated in a fire drill or emergency drill since starting at the facility. - The facility was to have fire drills or emergency drills twice per year. 3. During an interview on 08/14/18 at 2:50 PM, Staff F, Licensed Practical Nurse, stated that: - She was from a staffing agency but worked full time hours at the facility and had done so since 07/19/18. - She had not participated in a fire or emergency drill since starting at the facility. - When asked if she knew where the designated safe spot during a tornado was she replied she did not know. - When asked if she knew how to activate the fire alarm she stated she did not know.	L1081		
L1084	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the	L1084		

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L1084	Continued From page 2 exam rooms; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. - Recommendation II.b. * All horizontal surfaces in the operating room (OR) (e.g., furniture, surgical lights, booms, equipment) should be damp dusted before the first scheduled surgical or other invasive procedure of the day. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. 2. Review of the facility's "Infection Prevention	L1084		

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L1084	Continued From page 3	L1084		

Manual," dated 08/15, showed infection control resources included:
- Centers for Disease Control (CDC);
- Association for Professionals in Infection Control and Epidemiology (APIC); and
- AORN.

3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed:
- Thoroughly clean all surfaces that are used in patient care areas.
- Avoid cleaning methods and machines that re-suspend dust from surfaces, especially in patient care areas.
- All areas of the clinic should be kept clean and free from excess clutter.
- The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment.

4. Observation on 08/13/18 at 10:40 AM of the procedure room showed the metal suction machine cabinet had numerous rusted areas (uncleanable surface).

During an interview on 08/14/18 at 1:25 PM, Staff C, Health Center Manager, stated that she had cleaned the metal suction cabinet and confirmed it was rusted.

5. Observation on 08/13/18 at 10:45 AM of the recovery room medication supply room showed:
- A metal shelf unit with five pressed wood shelves, the shelves were dusty;
- A pressed wood shelf leaning against the wall;
- The floor under the shelf unit was dusty; and
- There was a box containing 25 expired hCG Urine Cassette Cultures (urine pregnancy test)

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L1084	Continued From page 4 expiration 03/18, on the floor behind the shelving unit. During an interview upon the observation, Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) stated that housekeeping staff did not have access to the room and confirmed that the urine pregnancy tests were expired. 6. Observation on 08/13/18 at 2:10 PM of exam room 1 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue which created a noncleanable surface; - Dust and debris and a brown stained area in the cabinet under the sink ; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; and - The gooseneck lamp had a dried peeling label and adhesive residue. 7. Observation on 08/13/18 at 2:15 PM of exam room 2 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue; - Dust and debris and a grayish black discolored area in the cabinet under the sink and an area where the base of the cabinet was peeling; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; - A plastic glove box holder had dust on the top	L1084		

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L1084	Continued From page 5 that left a visible mark when a finger was drawn through; and - The cabinet under the sink had peeling and/or missing laminate at the bottom outer corner. 8. Observation on 08/13/18 at 2:20 PM of exam room 3 showed the top edges of two picture frames were dusty. 9. During an interview on 08/13/18 at 2:25 PM, Staff C stated that: - The housekeeper did not go into the recovery room supply cabinet; - Peeling laminate could not be disinfected; and - They planned to purchase new tables for the exam rooms. 10. Observation on 08/13/18 at 2:30 PM of the soiled area showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue.	L1084		
L1090	19 CSR 30-30.060(1)(B)(7)(E) Provisions for licensed personnel to have cur Provisions for licensed personnel to have current cardiopulmonary (CPR) training so that at least one (1) licensed and trained personnel is at the facility at all times when patients are present for abortions; and This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that licensed personnel maintained current cardiopulmonary (CPR) training for one (B) of two licensed staff personnel records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four	L1090		

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L1090	Continued From page 6 procedures. Findings included: 1. Review of the facility's policy titled, "Personnel Files," dated 05/15, showed personnel information collected by the facility included first aid/CPR cards. 2. Review of Staff B, Registered Nurse (RN), Nurse Practitioner's (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) personnel file showed her CPR training had expired 04/20/18. 3. During an interview on 08/14/18 at 1:30 PM, Staff B stated that: - She was required to maintain current CPR. - She was not aware her CPR certification had expired.	L1090		
L1101	19 CSR 30-30.060(2)(B) Each patient shall be given all the informati Each patient shall be given all the information required by sections 188.027 and 188.039, RSMo, in the formats and timeframes required, by the type of professional required. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to ensure that the physician who was to perform or induce the abortion or a qualified professional as required by law (Section 188.027.1(1), RSMO, a physician, physician assistant, registered nurse, licensed practical nurse, psychologist, licensed professional counselor or licensed social worker licensed or registered and working under the	L1101		

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L1101	Continued From page 7	L1101		

supervision of the physician performing or inducing the abortion) informed the woman of the gestational age of the fetus at the time of abortion for ten (#1, #2, #3, #4, #5, #6, #7 #8, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures.

Findings included:

1. Review of Missouri law 188.027 RSMo, showed consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion:
(1) The physician who is to perform or induce the abortion, a qualified professional, or the referring physician has informed the woman orally, reduced to writing, and in person, of the following:
(f) The gestational age (term used during pregnancy to describe how far along the pregnancy is) of the unborn child at the time the abortion is to be performed or induced; and
(g) The anatomical (relating to bodily structure) and physiological (relating to organs and functions of the body) characteristics of the unborn child at the time the abortion is to be performed or induced.

2. Review of the facility's policy titled, "Patient Consent Policy," dated 06/18, showed:
- It is the policy of the Abortion Facility to comply with all applicable federal, state, and local laws and regulation in providing abortion care.
- The physician who will perform the abortion is required to provide the following information to a patient orally and in person at least seventy-two

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L1101	Continued From page 8 hours before the abortion procedure: * The unborn child's gestational age. (Note: The policy failed to specify the gestational age at the time of the abortion.) 3. Review of medical records showed: - The Seventy-two Hour Informed Consent was documented on 04/16/18 for Patient #1, #2, and #3 and the abortion was performed on 04/30/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 4/30/18 for Patient #4, #5, and #6 and the abortion was performed on 05/14/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 06/04/18 for Patient #8 and #9 and the abortion was performed on 06/18/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 05/14/18 for Patient #8 and the abortion was performed on 05/21/18, 7 days after the ultrasound was performed.. - The Seventy-two Hour Informed Consent was documented on 07/23/18 for Patient #10 and the abortion was performed on 07/30/18, 7 days after the ultrasound was performed. (Note: The gestational age presented to the pregnant woman at the time of the seventy-two hour consent visit was based on the determination of gestational age by ultrasound on that day and not the gestational age of the unborn child at the time of abortion.) 4. During an interview on 08/14/18 at approximately 1:30 PM, Staff B, Registered Nurse (RN), Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor), stated that:	L1101		

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L1101	Continued From page 9 - During the abortion education at the seventy-two hour informed consent visit the woman is given the gestational age of the embryo (a human offspring during the period from approximately the second to the eighth week after fertilization) based on her last menstrual period and told the gestational age would be confirmed by ultrasound. - The gestational age that is discussed is based on the ultrasound results at the time of the seventy-two hour visit, not the procedure date. - The day of procedure they go over gestational age again and discuss it but they do not use the Missouri Informed Consent Booklet or show them pictures of the gestational age of the unborn infant.	L1101		
L1119	19 CSR 30-30.060(3)(B) The facility shall maintain a medical record The facility shall maintain a medical record according to professional standards for each patient. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure discharge instructions were included in the medical record for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed:	L1119		

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L1119	Continued From page 10 - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 through 07/30/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained documentation of the discharge instructions provided to the patient. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - Discharge instructions were provided in the form of written instructions given to the patient: * "Surgical Abortion Discharge Instructions" including what was normal and what was abnormal, and staff contact numbers in the event of questions, concerns or an emergency; * "How Much Am I Bleeding," and * Instructions for taking prescribed medications. - The facility did not retain a copy of the instructions or include them in the medical record.	L1119		
L1120	19 CSR 30-30.060(3)(C) All medical record entries shall be timed All medical record entries shall be timed, dated, and signed or authenticated by the person making the entry.	L1120		

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L1120	Continued From page 11 This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure medication orders were timed, dated and signed by the ordering practitioner for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * II.J The medical record shall contain physician orders. All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry. (Note: The policy failed to address the need for medication orders, to be dated, timed and signed or authenticated by the person ordering the medications.) 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 for surgical abortion procedures showed the facility failed to ensure medication orders were signed, dated and timed by the ordering physician. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - She was aware the medication orders should	L1120		

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L1120	Continued From page 12 be timed, dated and signed by the physician when they were ordered. - The facility had developed a standard order set for medications but it had not been approved to be implemented.	L1120		
L1122	19 CSR 30-30.060(3)(D)(1) Documentation with a unique identifying recor Documentation with a unique identifying record number; patient identifying information; name of physician; diagnosis; medical history and physical examination record; laboratory reports; anesthesia administered; allergies/drug reactions; physician's orders; clinical notes; counseling notes; patient consent form; medication administration records; and discharge summary; This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that the physician documented the abortion counseling notes in the medical record for three (#3, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the facility's policy titled, "Medical Standards and Guidelines," dated 06/16 showed: - 1.2 Surgical Abortion: * 1.2.1 Patient Education and Informed Consent: All written materials given to the patient must be documented in record.	L1122		

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L1122	Continued From page 13 2. Review of the medical records for Patient #3, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 showed the records did not contain the physician counseling notes. 3. During an interview on 04/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The physician was responsible for documenting the abortion counseling that was performed during the initial patient visit in the medical record. - The medical records for Patients #3, #9, and #10 did not contain the required abortion counseling documentation.	L1122		
L1124	19 CSR 30-30.060(3)(D)(3) Method used to determine gestational age Method used to determine gestational age; gestational age; informed consent checklist required by section 188.027.3, RSMo; copy of abortion report required by section 188.052, RSMo, and 19 CSR 10-15.010; for surgical abortions, copy of tissue report required by section 188.047, RSMo, and 19 CSR 10-15.030; where applicable, copy of complication report required by section 188.052, RSMo, and 19 CSR 10-15.020; and This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure a copy of the abortion report was included in the medical record for two (#4 and #6) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases.	L1124		

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L1124	Continued From page 14 Findings included: 1. Review of Missouri law 188.052 RSMo, showed: - 1. An individual abortion report for each abortion performed or induced upon a woman shall be completed by her attending physician. - 4. A copy of the abortion report shall be made a part of the medical record of the patient of the facility or hospital in which the abortion was performed. 2. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 3. Review of the medical records for Patient #4, and #6 with an admission date of 05/14/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained a copy of the abortion report. 4. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The medical records for Patient #4 and #6 did not contain an abortion report. - Facility staff had failed to ensure a copy of the abortion report was included in the medical records for Patient #4 and #6.	L1124		

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L1130	Continued From page 15	L1130		
L1130	19 CSR 30-30.060(4) Infection Control Program Infection Control Program. The facility shall establish a comprehensive program for identifying and preventing infections. The infection control program shall be appropriate for scope and type of abortion procedures performed at the facility. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to ensure staff followed acceptable standards of practice for hand hygiene. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 2. Review of the Association for Professionals in	L1130		

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L1130	Continued From page 16 Infection Control and Epidemiology (APIC) scientific guidelines referred to in the CDC Morbidity and Mortality Weekly Report titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed the following: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 3. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Hand Hygiene," dated 2017, showed: - Recommendation I.d.4. * In the absence of visible soil, hands should be disinfected with an alcohol-based hand rub rather than washed with soap and water. - Recommendation III. * Perioperative team members should perform hand hygiene. - Recommendation III.a. * Personnel should perform hand hygiene: Before and after patient contact; Before performing a clean or sterile task; After risk for blood or body fluid exposure; After contact with patient surroundings; and When hands are visibly soiled. - Recommendation III.a.1. * Hand hygiene should be performed before and after patient contact, including:	L1130		

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L1130	Continued From page 17 Performing a physical exam; Marking the site; Transferring or positioning the patient; Assessing an invasive device (e.g., vascular catheter [peripheral, arterial, central], urinary catheter); and Assessing wound dressing. - Recommendation III.a.2. * Hand hygiene should be performed before a clean or sterile task, including: Inserting an invasive device (e.g., vascular catheter [peripheral, arterial, central] urinary catheter); Assessing a vascular device (e.g., port, stopcock, IV tubing); Moving from a contaminated body site (e.g., perineum) to a clean body site (e.g., face) on the same patient; Opening sterile supplies; and Performing patient skin antisepsis. - Recommendation III.a.3. * Hand hygiene should be performed after risk for blood or body fluid exposure, including: Removing personal protective equipment (e.g., gloves, mask); Having contact with blood, body fluids, excretions, mucous membranes, non-intact skin, or wound dressings; - Recommendation III.a.4. * Hand hygiene should be performed after contact with patient surroundings, including: Inanimate surfaces and objects, including medical equipment, in the immediate vicinity of the patient; Operating room (OR) bed controls; and Patient bed and linens. - Recommendation III.a.5. * The use of gloves does not replace the need for hand hygiene.	L1130		

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L1130	Continued From page 18 - Recommendation III.d. * When hands are not visibly soiled or dirty, hand hygiene should be performed using an alcohol-based hand rub according to the manufacturer's instructions for use. 4. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - CDC; - APIC; and - AORN. 5. Review of the facility's "Infection Prevention Manual" policy titled, "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE)," dated 08/15, showed: - Hand hygiene should be performed when hands are visibly soiled with blood or other body fluids, wash hands with water and soap. Wash hands even prior to donning gloves. - If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under "hand hygiene" above. 6. Observation on 08/13/18 from approximately 10:12 AM to 10:30 AM of Patient #11's abortion procedure showed Staff BB, Physician: - Entered the room, donned gloves and performed a manual vaginal exam; - Changed her gloves, did not perform hand hygiene, and performed a speculum (medical tool inserted into the vagina to dilate it for examination of the vagina and cervix) exam; - Picked up a bottle of spray vinegar solution and sprayed the solution in the patient's vaginal area; - Picked up a syringe of Lidocaine (numbing	L1130		

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L1130	Continued From page 19	L1130		

medication) and injected it into the patient's vaginal/cervix area;
- Disposed of the medication syringe, removed her soiled gloves, and donned sterile gloves without performing hand hygiene;
- Completed the abortion, cleansed the patient's vaginal area, removed her bloody gloves, failed to perform hand hygiene, and donned nonsterile gloves;
- Exited the room; and
- Carried the product of conception to the soiled area, examined the product of conception, removed her gloves, and performed hand hygiene.

7. Observation on 08/13/18 from approximately 11:10 AM to 11:35 AM of Patient #12's procedure showed Staff BB, Physician:
- Entered the room, examined the patient's medical record and donned a single glove, she failed to perform hand hygiene before donning the glove;
- Performed an abdominal ultrasound (test that uses sound waves to make images within the abdomen to determine the size/age of the fetus) on the patient, removed the glove, and failed to perform hand hygiene;
- Wiped the ultrasound gel off the patient's abdomen and had the patient sign paperwork; and
- Picked up the patient's medical record, reviewed the consent with the patient, had the patient sign the consent, Staff BB signed the consent, and exited the room without performing hand hygiene.

8. Observation on 08/13/18 from approximately 11:53 AM to 12:05 PM of Patient #13's lab visit for blood and urine testing showed Staff F,

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L1130	Continued From page 20 Licensed Practical Nurse: - Performed hand hygiene and donned gloves, moved a urine specimen cup from the wall cabinet to the sink, removed her gloves, and donned clean gloves. She failed to perform hand hygiene between gloves changes; - Tested the urine, removed her gloves and performed hand hygiene and documented in the medical record; and - Donned clean gloves without performing hand hygiene, obtained a blood sample, checked the blood sample and removed her gloves. She failed to perform hand hygiene after removing her gloves. 9. Observation on 08/13/18 at 2:00 PM showed: - Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) performed hand hygiene upon entering the room, obtained lab supplies to obtained a blood specimen; - Donned gloves, failed to perform hand hygiene prior to donning the gloves; - Drew blood from Patient #13, removed her gloves, failed to perform hand hygiene; - Escorted the patient to the door; and - Took the patient's medical record to the lab.	L1130		

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 08/13/18 to 08/14/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L1081	19 CSR 30-30.060(1)(B)(3) The administrator shall be responsible, plan The administrator shall be responsible for developing a written plan for evacuation of patients and personnel in the event of fire, explosion, active shooter, or other disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. Disaster drills with participation of all staff shall be conducted and documented at least annually. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that all staff participated in drills and were knowledgeable about the plan. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's document titled, "Quarterly Fire Drill Report," dated 02/18/18, showed that the facility had a fire drill on that date. The previous fire drill was held on 04/05/17. 2. During an interview on 08/14/18 at 2:33 PM,	L1081		

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L1081	Continued From page 1 Staff C, Health Center Manager, stated that: - She had been employed at the facility since March. - She had not participated in a fire drill or emergency drill since starting at the facility. - The facility was to have fire drills or emergency drills twice per year. 3. During an interview on 08/14/18 at 2:50 PM, Staff F, Licensed Practical Nurse, stated that: - She was from a staffing agency but worked full time hours at the facility and had done so since 07/19/18. - She had not participated in a fire or emergency drill since starting at the facility. - When asked if she knew where the designated safe spot during a tornado was she replied she did not know. - When asked if she knew how to activate the fire alarm she stated she did not know.	L1081		
L1084	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the	L1084		

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L1084	Continued From page 2 exam rooms; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. - Recommendation II.b. * All horizontal surfaces in the operating room (OR) (e.g., furniture, surgical lights, booms, equipment) should be damp dusted before the first scheduled surgical or other invasive procedure of the day. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. 2. Review of the facility's "Infection Prevention	L1084		

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L1084	Continued From page 3 Manual," dated 08/15, showed infection control resources included: - Centers for Disease Control (CDC); - Association for Professionals in Infection Control and Epidemiology (APIC); and - AORN. 3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed: - Thoroughly clean all surfaces that are used in patient care areas. - Avoid cleaning methods and machines that re-suspend dust from surfaces, especially in patient care areas. - All areas of the clinic should be kept clean and free from excess clutter. - The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment. 4. Observation on 08/13/18 at 10:40 AM of the procedure room showed the metal suction machine cabinet had numerous rusted areas (uncleanable surface). During an interview on 08/14/18 at 1:25 PM, Staff C, Health Center Manager, stated that she had cleaned the metal suction cabinet and confirmed it was rusted. 5. Observation on 08/13/18 at 10:45 AM of the recovery room medication supply room showed: - A metal shelf unit with five pressed wood shelves, the shelves were dusty; - A pressed wood shelf leaning against the wall; - The floor under the shelf unit was dusty; and - There was a box containing 25 expired hCG Urine Cassette Cultures (urine pregnancy test)	L1084		

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L1084	Continued From page 4 expiration 03/18, on the floor behind the shelving unit. During an interview upon the observation, Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) stated that housekeeping staff did not have access to the room and confirmed that the urine pregnancy tests were expired. 6. Observation on 08/13/18 at 2:10 PM of exam room 1 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue which created a noncleanable surface; - Dust and debris and a brown stained area in the cabinet under the sink ; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; and - The gooseneck lamp had a dried peeling label and adhesive residue. 7. Observation on 08/13/18 at 2:15 PM of exam room 2 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue; - Dust and debris and a grayish black discolored area in the cabinet under the sink and an area where the base of the cabinet was peeling; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; - A plastic glove box holder had dust on the top	L1084		

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L1084	Continued From page 5 that left a visible mark when a finger was drawn through; and - The cabinet under the sink had peeling and/or missing laminate at the bottom outer corner. 8. Observation on 08/13/18 at 2:20 PM of exam room 3 showed the top edges of two picture frames were dusty. 9. During an interview on 08/13/18 at 2:25 PM, Staff C stated that: - The housekeeper did not go into the recovery room supply cabinet; - Peeling laminate could not be disinfected; and - They planned to purchase new tables for the exam rooms. 10. Observation on 08/13/18 at 2:30 PM of the soiled area showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue.	L1084		
L1090	19 CSR 30-30.060(1)(B)(7)(E) Provisions for licensed personnel to have cur Provisions for licensed personnel to have current cardiopulmonary (CPR) training so that at least one (1) licensed and trained personnel is at the facility at all times when patients are present for abortions; and This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that licensed personnel maintained current cardiopulmonary (CPR) training for one (B) of two licensed staff personnel records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four	L1090		

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L1090	Continued From page 6 procedures. Findings included: 1. Review of the facility's policy titled, "Personnel Files," dated 05/15, showed personnel information collected by the facility included first aid/CPR cards. 2. Review of Staff B, Registered Nurse (RN), Nurse Practitioner's (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) personnel file showed her CPR training had expired 04/20/18. 3. During an interview on 08/14/18 at 1:30 PM, Staff B stated that: - She was required to maintain current CPR. - She was not aware her CPR certification had expired.	L1090		
L1101	19 CSR 30-30.060(2)(B) Each patient shall be given all the informati Each patient shall be given all the information required by sections 188.027 and 188.039, RSMo, in the formats and timeframes required, by the type of professional required. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to ensure that the physician who was to perform or induce the abortion or a qualified professional as required by law (Section 188.027.1(1), RSMO, a physician, physician assistant, registered nurse, licensed practical nurse, psychologist, licensed professional counselor or licensed social worker licensed or registered and working under the	L1101		

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	A004	A. BUILDING: _____ B. WING _____	08/14/2018

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L1101	Continued From page 7 supervision of the physician performing or inducing the abortion) informed the woman of the gestational age of the fetus at the time of abortion for ten (#1, #2, #3, #4, #5, #6, #7 #8, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of Missouri law 188.027 RSMo, showed consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion: (1) The physician who is to perform or induce the abortion, a qualified professional, or the referring physician has informed the woman orally, reduced to writing, and in person, of the following: (f) The gestational age (term used during pregnancy to describe how far along the pregnancy is) of the unborn child at the time the abortion is to be performed or induced; and (g) The anatomical (relating to bodily structure) and physiological (relating to organs and functions of the body) characteristics of the unborn child at the time the abortion is to be performed or induced. 2. Review of the facility's policy titled, "Patient Consent Policy," dated 06/18, showed: - It is the policy of the Abortion Facility to comply with all applicable federal, state, and local laws and regulation in providing abortion care. - The physician who will perform the abortion is required to provide the following information to a patient orally and in person at least seventy-two	L1101		

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L1101	Continued From page 8 hours before the abortion procedure: * The unborn child's gestational age. (Note: The policy failed to specify the gestational age at the time of the abortion.) 3. Review of medical records showed: - The Seventy-two Hour Informed Consent was documented on 04/16/18 for Patient #1, #2, and #3 and the abortion was performed on 04/30/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 4/30/18 for Patient #4, #5, and #6 and the abortion was performed on 05/14/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 06/04/18 for Patient #8 and #9 and the abortion was performed on 06/18/18, 14 days after the ultrasound was performed. - The Seventy-two Hour Informed Consent was documented on 05/14/18 for Patient #8 and the abortion was performed on 05/21/18, 7 days after the ultrasound was performed.. - The Seventy-two Hour Informed Consent was documented on 07/23/18 for Patient #10 and the abortion was performed on 07/30/18, 7 days after the ultrasound was performed. (Note: The gestational age presented to the pregnant woman at the time of the seventy-two hour consent visit was based on the determination of gestational age by ultrasound on that day and not the gestational age of the unborn child at the time of abortion.) 4. During an interview on 08/14/18 at approximately 1:30 PM, Staff B, Registered Nurse (RN), Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor), stated that:	L1101		

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L1101	Continued From page 9 - During the abortion education at the seventy-two hour informed consent visit the woman is given the gestational age of the embryo (a human offspring during the period from approximately the second to the eighth week after fertilization) based on her last menstrual period and told the gestational age would be confirmed by ultrasound. - The gestational age that is discussed is based on the ultrasound results at the time of the seventy-two hour visit, not the procedure date. - The day of procedure they go over gestational age again and discuss it but they do not use the Missouri Informed Consent Booklet or show them pictures of the gestational age of the unborn infant.	L1101		
L1119	19 CSR 30-30.060(3)(B) The facility shall maintain a medical record The facility shall maintain a medical record according to professional standards for each patient. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure discharge instructions were included in the medical record for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed:	L1119		

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L1119	Continued From page 10 - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 through 07/30/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained documentation of the discharge instructions provided to the patient. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - Discharge instructions were provided in the form of written instructions given to the patient: * "Surgical Abortion Discharge Instructions" including what was normal and what was abnormal, and staff contact numbers in the event of questions, concerns or an emergency; * "How Much Am I Bleeding," and * Instructions for taking prescribed medications. - The facility did not retain a copy of the instructions or include them in the medical record.	L1119		
L1120	19 CSR 30-30.060(3)(C) All medical record entries shall be timed All medical record entries shall be timed, dated, and signed or authenticated by the person making the entry.	L1120		

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L1120	Continued From page 11 This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure medication orders were timed, dated and signed by the ordering practitioner for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * II.J The medical record shall contain physician orders. All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry. (Note: The policy failed to address the need for medication orders, to be dated, timed and signed or authenticated by the person ordering the medications.) 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 for surgical abortion procedures showed the facility failed to ensure medication orders were signed, dated and timed by the ordering physician. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - She was aware the medication orders should	L1120		

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L1120	Continued From page 12 be timed, dated and signed by the physician when they were ordered. - The facility had developed a standard order set for medications but it had not been approved to be implemented.	L1120		
L1122	19 CSR 30-30.060(3)(D)(1) Documentation with a unique identifying recor Documentation with a unique identifying record number; patient identifying information; name of physician; diagnosis; medical history and physical examination record; laboratory reports; anesthesia administered; allergies/drug reactions; physician's orders; clinical notes; counseling notes; patient consent form; medication administration records; and discharge summary; This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that the physician documented the abortion counseling notes in the medical record for three (#3, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the facility's policy titled, "Medical Standards and Guidelines," dated 06/16 showed: - 1.2 Surgical Abortion: * 1.2.1 Patient Education and Informed Consent: All written materials given to the patient must be documented in record.	L1122		

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L1122	Continued From page 13 2. Review of the medical records for Patient #3, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 showed the records did not contain the physician counseling notes. 3. During an interview on 04/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The physician was responsible for documenting the abortion counseling that was performed during the initial patient visit in the medical record. - The medical records for Patients #3, #9, and #10 did not contain the required abortion counseling documentation.	L1122		
L1124	19 CSR 30-30.060(3)(D)(3) Method used to determine gestational age Method used to determine gestational age; gestational age; informed consent checklist required by section 188.027.3, RSMo; copy of abortion report required by section 188.052, RSMo, and 19 CSR 10-15.010; for surgical abortions, copy of tissue report required by section 188.047, RSMo, and 19 CSR 10-15.030; where applicable, copy of complication report required by section 188.052, RSMo, and 19 CSR 10-15.020; and This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure a copy of the abortion report was included in the medical record for two (#4 and #6) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases.	L1124		

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L1124	Continued From page 14 Findings included: 1. Review of Missouri law 188.052 RSMo, showed: - 1. An individual abortion report for each abortion performed or induced upon a woman shall be completed by her attending physician. - 4. A copy of the abortion report shall be made a part of the medical record of the patient of the facility or hospital in which the abortion was performed. 2. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 3. Review of the medical records for Patient #4, and #6 with an admission date of 05/14/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained a copy of the abortion report. 4. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The medical records for Patient #4 and #6 did not contain an abortion report. - Facility staff had failed to ensure a copy of the abortion report was included in the medical records for Patient #4 and #6.	L1124		

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L1130	Continued From page 15	L1130		
L1130	19 CSR 30-30.060(4) Infection Control Program Infection Control Program. The facility shall establish a comprehensive program for identifying and preventing infections. The infection control program shall be appropriate for scope and type of abortion procedures performed at the facility. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to ensure staff followed acceptable standards of practice for hand hygiene. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 2. Review of the Association for Professionals in	L1130		

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L1130	Continued From page 16 Infection Control and Epidemiology (APIC) scientific guidelines referred to in the CDC Morbidity and Mortality Weekly Report titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed the following: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 3. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Hand Hygiene," dated 2017, showed: - Recommendation I.d.4. * In the absence of visible soil, hands should be disinfected with an alcohol-based hand rub rather than washed with soap and water. - Recommendation III. * Perioperative team members should perform hand hygiene. - Recommendation III.a. * Personnel should perform hand hygiene: Before and after patient contact; Before performing a clean or sterile task; After risk for blood or body fluid exposure; After contact with patient surroundings; and When hands are visibly soiled. - Recommendation III.a.1. * Hand hygiene should be performed before and after patient contact, including:	L1130		

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L1130	Continued From page 17 Performing a physical exam; Marking the site; Transferring or positioning the patient; Assessing an invasive device (e.g., vascular catheter [peripheral, arterial, central], urinary catheter); and Assessing wound dressing. - Recommendation III.a.2. * Hand hygiene should be performed before a clean or sterile task, including: Inserting an invasive device (e.g., vascular catheter [peripheral, arterial, central] urinary catheter); Assessing a vascular device (e.g., port, stopcock, IV tubing); Moving from a contaminated body site (e.g., perineum) to a clean body site (e.g., face) on the same patient; Opening sterile supplies; and Performing patient skin antisepsis. - Recommendation III.a.3. * Hand hygiene should be performed after risk for blood or body fluid exposure, including: Removing personal protective equipment (e.g., gloves, mask); Having contact with blood, body fluids, excretions, mucous membranes, non-intact skin, or wound dressings; - Recommendation III.a.4. * Hand hygiene should be performed after contact with patient surroundings, including: Inanimate surfaces and objects, including medical equipment, in the immediate vicinity of the patient; Operating room (OR) bed controls; and Patient bed and linens. - Recommendation III.a.5. * The use of gloves does not replace the need for hand hygiene.	L1130		

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L1130	Continued From page 18 - Recommendation III.d. * When hands are not visibly soiled or dirty, hand hygiene should be performed using an alcohol-based hand rub according to the manufacturer's instructions for use. 4. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - CDC; - APIC; and - AORN. 5. Review of the facility's "Infection Prevention Manual" policy titled, "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE)," dated 08/15, showed: - Hand hygiene should be performed when hands are visibly soiled with blood or other body fluids, wash hands with water and soap. Wash hands even prior to donning gloves. - If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under "hand hygiene" above. 6. Observation on 08/13/18 from approximately 10:12 AM to 10:30 AM of Patient #11's abortion procedure showed Staff BB, Physician: - Entered the room, donned gloves and performed a manual vaginal exam; - Changed her gloves, did not perform hand hygiene, and performed a speculum (medical tool inserted into the vagina to dilate it for examination of the vagina and cervix) exam; - Picked up a bottle of spray vinegar solution and sprayed the solution in the patient's vaginal area; - Picked up a syringe of Lidocaine (numbing	L1130		

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L1130	Continued From page 19 medication) and injected it into the patient's vaginal/cervix area; - Disposed of the medication syringe, removed her soiled gloves, and donned sterile gloves without performing hand hygiene; - Completed the abortion, cleansed the patient's vaginal area, removed her bloody gloves, failed to perform hand hygiene, and donned nonsterile gloves; - Exited the room; and - Carried the product of conception to the soiled area, examined the product of conception, removed her gloves, and performed hand hygiene. 7. Observation on 08/13/18 from approximately 11:10 AM to 11:35 AM of Patient #12's procedure showed Staff BB, Physician: - Entered the room, examined the patient's medical record and donned a single glove, she failed to perform hand hygiene before donning the glove; - Performed an abdominal ultrasound (test that uses sound waves to make images within the abdomen to determine the size/age of the fetus) on the patient, removed the glove, and failed to perform hand hygiene; - Wiped the ultrasound gel off the patient's abdomen and had the patient sign paperwork; and - Picked up the patient's medical record, reviewed the consent with the patient, had the patient sign the consent, Staff BB signed the consent, and exited the room without performing hand hygiene. 8. Observation on 08/13/18 from approximately 11:53 AM to 12:05 PM of Patient #13's lab visit for blood and urine testing showed Staff F,	L1130		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
L1130	Continued From page 20 Licensed Practical Nurse: - Performed hand hygiene and donned gloves, moved a urine specimen cup from the wall cabinet to the sink, removed her gloves, and donned clean gloves. She failed to perform hand hygiene between gloves changes; - Tested the urine, removed her gloves and performed hand hygiene and documented in the medical record; and - Donned clean gloves without performing hand hygiene, obtained a blood sample, checked the blood sample and removed her gloves. She failed to perform hand hygiene after removing her gloves. 9. Observation on 08/13/18 at 2:00 PM showed: - Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) performed hand hygiene upon entering the room, obtained lab supplies to obtained a blood specimen; - Donned gloves, failed to perform hand hygiene prior to donning the gloves; - Drew blood from Patient #13, removed her gloves, failed to perform hand hygiene; - Escorted the patient to the door; and - Took the patient's medical record to the lab.	L1130		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

August 30, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains
711 N Providence Road
Columbia, MO 65203

RE: ***Licensure Survey TKOR11***

Dear Vicki Casey:

You will find enclosed one or more Statement(s) of Deficiency (SOD) Form-2567, which covers the findings of the survey conducted on ***August 14, 2018*** in connection with the ***State Licensure*** requirements as they pertain to abortion centers in Missouri.

The deficiencies are itemized on the enclosed Form-2567 Statement of Deficiency. An acceptable plan of correction and expected completion date must be entered for each deficiency clearly identifying ***how*** and ***when each*** deficiency will be corrected and ***who*** will be responsible for assuring and monitoring correction. The plan should also include ***provisions instituted*** to prevent recurrence of the deficiency. Use the space provided on the SOD, to the right of each deficiency, to indicate your plan of correction and the expected completion date.

Even though the deficiency may have been corrected before a plan of correction is returned to this office, you should still outline the plan of correction. The statement "corrected" or "completed" is not an acceptable response. If you anticipate that any of the corrections will take an extended period of time, it is recommended that you write a phased plan of correction, and include expected completion date(s) for each phase. If the phased plan is found to be acceptable, the surveyor(s) will evaluate your progress toward correcting the deficiency in accordance to the approved plan at the revisit.

Please sign and date the first page of the Form-2567 in the block labeled "Facility Representative's signature" and return it with your plan of correction to this office ***within ten (10) calendar days*** of the date it is received. Please retain a copy of the SOD for your own reference.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

Enclosure

Americans United for Life

MO Bureau of Ambulatory Care —Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date (from CMS 2567)	8/14/2018
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	State or Federal SOD Q-tags, L-tags, K-tags, E-tags	

1. **Include a copy of the first page of each of the original forms CMS-2567** Statement(s) of Deficiencies for Federal (Q-tags, E-tags), State (L-tags) and Life Safety (K-tags) **signed & dated by administrator** or designee, along with associated completed POC forms **no later than ten (10) calendar days from receipt of this document**. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. Complete a **separate POC form for each applicable regulation set of the Statement of Deficiencies** (Federal Q-tags, E-tags, State L-tags, and Life Safety K-tags).

3. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation for Q-tags, E-tags, L-tags, and K-tags.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form CMS-2567 "Statement of Deficiencies" (Q181, L224, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date, and generally **must be** no later than 60 days from Exit. *(Limited extensions may be granted upon written request should extraordinary circumstances exist.)* To allow for adequate time for correction of deficiencies, should an onsite revisit be necessary, correction **should be completed** less than 45 days from Exit.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D." above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

Americans United for Life

MO Bureau of Ambulatory Care — Facility Plan of Correction (POC) Form

A (TAG)	**B (CORRECTIVE ACTION)**	**C (WHEN)**	**D (WHO)**	**E (EVIDENCE OF COMPLIANCE)**	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1081	CHPPGP will conduct future drills to include both part-time ("PRN") employees and temporary contractors, if applicable, to ensure that all employees who may be on-site when CHPPGP is operating the Columbia facility are prepared for evacuation during a disaster.	8/22/2018 (actions already completed) and 10/1/2018 (additional action item)	Health center manager and facility administrator	The manager has reviewed the current written plan for evacuation of patients and personnel in the event of a fire, explosion, active shooter or other disaster with Regional Director (facility administrator). Staff completed drills in preparation for emergencies on 8/21/2018 (active shooter training with third-party vendor) and 8/22/2018 (fire, tornado, and bomb threat) to ensure compliance. Because the active shooter training was provided by an outside party while CHPPGP's physician was not at the health center, an additional drill will be conducted while the physician is in attendance on or before October 1, 2018.	*See* Exhibit A (attached).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP will take the following steps in response to the items identified in this finding: 1. **Arrange an in-person meeting with its environmental services cleaning provider to review its expectations and standards.** Health center manager; regional director of health center operations (administrator); and vice president of operations, will attend the meeting and review with the environmental services provider each of the areas identified in DHSS's report. This step is designed to address the dust-related portions of the finding. 2. **Document on a log the daily inspection performed by personnel at the facility prior to seeing patients.** The log will be maintained for 30 days by manager and submitted to regional director for review. This step is designed to address the dust-related portions of the finding and to ensure that expired tests that are not intended for future use are disposed of in a timely manner.	Item 1 will occur within 30 days of the submission of this POC. Item 2 will commence on 10/15/18, be evaluated daily, and conclude on 11/14/18.	Vice president of operations Manager and administrator	Item 1, a one-time meeting, will be monitored by center manager and regional director of health services operations. Item 2 will be monitored on a daily basis by manager, and on a weekly basis by regional director of health services operations (administrator).	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	3. **Administrator and VP of Operations will review with CHPPGP's facilities coordinator the following issues:** 1) Rusted areas on cabinet in observation 4; shelf in observation 5; peeling label and adhesive on chart holder and lamp, debris and stain under sink, and chipped paint in observation 6; peeling label and adhesive, debris and mark under sink, peeling on base of cabinet, chipped paint on pressed wood, and chipped laminate in observation 7; and residue under sink in observation 10. The facilities coordinator will outline a process for repair and/or replacement for those items.	The meeting outlined in Item 3 will be concluded by 10/1/18, and repairs/replacements will be concluded by October 31, 2018.	Vice president of operations	Item 3 will be monitored by vice president for operations. In addition to scheduling the initial meeting, vice president for operations will oversee repairs and/or replacements, as necessary.	

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1090	CHPPGP objects to the deficiency in L1090, as at all times during which it operated in 2017-2018 at least one licensed employee with current CPR training was onsite, as required by regulation. CHPPGP provided to surveyors copies of CHPPGP personnel files for those employees involved in the provision of abortion care, and those files reflect current CPR training for multiple individuals.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1101	CHPPGP objects to the deficiency identified in L1101. Pursuant to state law, CHPPGP provides to patients required information at the time of their state-mandated first visit, which must occur at least 72 hours prior to the performance of an abortion procedure. CHPPGP also is required and does provide to patients Missouri's Informed Consent Booklet, which by statute must include "probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from conception to full term, including color photographs or images of the developing unborn child at two-week gestational increments." § 188.027(2), RSMo. That booklet, provided to each patient, fulfills this requirement as it outlines state-mandated descriptions of changes in gestational age from the date of a patient's first visit to her second visit. CHPPGP will ensure appropriate staff specifies during the first visit that, because of the state-mandated delay, the patient's pregnancy is anticipated to be at a certain point when she	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	returns, and the state-created description of the fetus at that future gestation is in the Missouri Informed Consent Booklet. If, for some reason, a patient needs to reschedule her appointment, the booklet will also contain the state-created description of the fetus for that later time.				

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1119	CHPPGP objects to the deficiency identified in L1119 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that each patient receiving abortion care is provided with discharge instructions that include the following hand-outs: 1) How Much Am I Bleeding? (describing post-procedure normal and abnormal bleeding); 2) medication instructions; and 3) and surgical abortion discharge instructions, which include the facility's after-hours telephone number. DHSS's report does not state, however, that an entry is made by CHPPGP personnel in each patient's medical record that the patient received copies of those documents. That entry satisfies the regulation's requirement that written discharge instructions be provided to patients.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1120	CHPPGP objects to the deficiency identified in L1120 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that the physician providing care signed and dated the visit summary generated by the electronic health record, which reflects the medications prescribed during the patient encounter. To CHPPGP's knowledge, DHSS has not prior to its 2018 inspections interpreted this regulation to require each separate portion of a patient's medical record be signed and authenticated by the treating physician. As CHPPGP noted during the on-site inspection, however, it created a hard copy form in response to the inspection at its Kansas City facility. This form will provide an additional place for the physician to sign, date, and time medication orders for each patient and will be scanned into the medical record. This entry will be duplicative of that information on the patient's visit summary.	*In progress*	Administrator	The form has already been developed and is in use. The center manager will review electronic health records for all patients receiving abortion care for one month after the form has been in use to monitor for compliance.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1122	CHPPGP objects to the deficiency identified in L1122 to the extent it misstates the nature of the information conveyed during the survey process. For each of the patient records reviewed by the surveyor, a physician or qualified health professional (as defined by § 188.027, RSMo) provided the state-mandated information to patients receiving abortion care. The records described in L1122 reflected that persons meeting the statutory and regulatory definitions gave the required information. CHPPGP's physician *elected* to note in a number of patient records that she had delivered state-mandated information; however, that notation was only intended to duplicate what the other records in each patient's record showed: that required personnel delivered the information. CHPPGP's physician simply went above and beyond by reiterating that she had followed state law. To the extent that notation creates confusion for DHSS, CHPPGP will note for its provider that the notation is not necessary.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1124	CHPPGP objects to the deficiency identified in L1122 *in part* to the extent it misstates the nature of the information conveyed during the survey process. At the time of inspection, two state-mandated reports, Induced Termination of Pregnancy (ITOP) reports, had already been submitted to DHSS as required but had not yet been scanned into the patients' electronic medical record. CHPPGP staff located both reports on the day of inspection, and they have since been scanned into the patients' electronic records. Additionally, CHPPGP has revised its indexing process. Administrative personnel continue to handle the submission of ITOP reports to DHSS, but the center manager now submits reports for each procedure by the close of business on the day the procedures were performed.	Completed 8/15/2018	Center manager and regional director (administrator)	Regional Director will be responsible for monitoring new process and verifying that all ITOP reports are submitted pursuant to revised procedure.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1130	The director of clinical quality risk management will conduct a comprehensive training with facility staff to serve as a refresher course on CHPPGP's infection control program. CHPPGP's health center manager will also perform quarterly audits to ensure ongoing compliance after the education session.	Training will be conducted by 9/30/2018	Director of clinical quality risk management and administrator	Regional director (administrator) will conduct unannounced audits after completion of training on a quarterly basis.	N/A

Emergency Drill Attendance
August 22, 2018
Fire, Tornado, Bomb Threat

[redacted] HCM

[redacted] Lead Office Assistant

[redacted] NP

[redacted] LPN

[redacted] LPN Temp

[redacted] Assistant VP of Health Services

[redacted] VP of Health Services

[redacted] Grassroots Organizer

[redacted] Lobbyist

Dr. [redacted]

[redacted] Security officer

[redacted]

Americans United for Life

Bomb Threat Drill Report
Semi-Annual

Center: COLUMBIA Date: 8/22/18 Time of Threat: 12:20

Staff Receiving Threat: Drill

Staff Present: [redacted]

Yes	No	Staff receiving threat notified Center Manager/designee [redacted]
Yes	No	Bomb Threat instructions posted at phone
Yes	No	Phone guidelines followed and appropriate data recorded
Yes	No	Manager notified Security Director or next level supervision
Yes	No	Police/Fire Department notified
Yes	No	Control Center Established
Yes	No	Search area assignments made
Yes	No	NO light switches are disturbed
Yes	No	All areas checked per pre-determined checklist for the center
Yes	No	Suspicious item(s) found; item(s) not moved or touched
Yes	No	If yes, manager informed and decision made to evacuate/not evacuate

Discussed

Comments: Drill, no threat received

Staff: [redacted] Title: Health Center Manager

Americans United for Life

Fire Drill Report
Semi-Annual

Center: COLUMBIA Date: 6/22/18 **Time Started:** 12:30 **Time Ended:** _____

STAFF PRESENT: [redacted]

Alarm Performance

How was drill initiated? Fire alarm pull station_____ Smoke Alarm_____ Verbal

Location of fire alarm station/smoke alarm used Pointed out

What technique was used to indicate fire? ~~Clock~~ 0

Drill Type: Audible alarm_____ Coded/silent alarm_____

Date alarm audibly tested (if not tested during the drill): 6/26/18

Did all staff hear the alarm? (Yes) No

Did all fire emergency equipment function properly? (Yes) No

What time did dispatch receive the alarm: 0

Personnel Performance

RESCUE

(Yes)	No	Were all the staff, patients and visitors evacuated from the fire zone?
(Yes)	No	Was the proper/systematic search conducted
(Yes)	No	Did staff account for all patients?
(Yes)	No	Duties Divided as needed

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ALARM

Who activated the alarm? Protection 1

Yes No Was the alarm properly activated?

Yes No Did staff call the fire department? but discussed

Yes No Was the alarm reset?

CONTAINMENT

Yes No Did staff close office doors?

Yes No Were corridor doors unobstructed?

Yes No Did all corridor doors latch properly?

EXTINGUISHMENT/EVACUATION

Yes No Were proper fire extinguishers taken to fire area?

Yes No Did staff simulate using a fire extinguisher?

Yes No Did staff stay with evacuated patients?

Yes No If a "large" fire, were evacuation plans followed?

Yes No How long did it take to secure/evacuate all areas?

Discussed

COMMENTS/SENERIO:

Staff: [redacted] Title: Health Center Manager

Americans United for Life

Tornado Drill Report
Semi-Annual

Center: COLUMBIA Date: 8/22/18 Time Started: 12:10 Time Ended: _____

Staff Present: [redacted]

Number of Patients: 0

Yes No Were patients and staff moved to an area designated as safe?

Yes No Radio on and turned to station providing the weather

Yes No Staff hearing alert notified Center Manager or assumed responsibility

Yes No Duties Divided as needed

Yes No Staff assured all patients informed/moved and instruction were given

Yes No All staff knew designated areas. (Bathrooms, store room, break room, etc.)

Yes No All patient records secure

Yes No All cash receipts and cash secure

Yes No Emergency lights and equipment were available, accessible, and operational

Flashlights Emergency lighting Blankets First aid kit

Yes No Need for medical care assessed

Yes No Damage to building assessed and action taken to assure no other danger present

Comments: Drill, no threat received

Staff: [redacted] Title: Health Center Manager

Americans United for Life

REMOVE STUB - SEPARATE FORMS BEFORE FILLING OUT

[redacted]

FIRE INSPECTION AND TESTING REPORT

Customer Number [redacted] Telephone Number [redacted] Branch Number ____ Contract Number ____

CS Number [redacted] Site Number ____ Job Number [redacted]

Customer Last Name Planned Parenthood First Name ____ MI ____ Today's Date ____

Site Address 711 N Providence City Columbia State MO Zip Code 65203

Billing Address (if different from above) ____ City ____ State ____ Zip Code ____

TYPE TRANSMISSION
- McCulloh
- Multiplex
- Digital
- Reverse Priority
- RF
- Other (Specify) [redacted]

Control Unit Manufact. [redacted]
Circuit Styles:
Number of Circuits:
Software Rev.:

SERVICE
- Weekly
- Monthly
- Quarterly
- Semiannually
- Annually
- Other (Specify) ____

Model No.: ____

Last Date System Had Any Service Performed: ____
Last Date That Any Software or Configuration Was Revised: ____

ALARM-INITIATING DEVICES AND CIRCUIT INFORMATION

Quantity of Devices Installed	Circuit Style	Quantity of Devices Tested	
3	B	1	Manual Fire Alarm Boxes
12	B	2	Ion Detectors
1	B		Photo Detectors
1	Serial	1	Duct Detectors
1	Serial		Heat Detectors
			Waterflow Switches
			Supervisory Switches
			Other (Specify): ____

Alarm verification feature is [redacted]

ALARM NOTIFICATION APPLIANCES AND CIRCUIT INFORMATION

Quantity of Appliances Installed	Circuit Style	Quantity of Appliances Tested	
9	B		Bells
9	B		Horns
			Chimes
			Strobes
			Speakers
			Other (Specify): ____

No. of alarm notification appliance circuits: ____
Are circuits monitored for integrity? ☐ Yes ☐ No

SUPERVISORY SIGNAL-INITIATING DEVICES AND CIRCUIT INFORMATION

Quantity of Devices Installed	Circuit Style	Quantity of Devices Tested	
			Building Temp.
			Site Water Temp.
			Site Water Level
			Fire Pump Power
			Fire Pump Running
			Fire Pump Auto Position
			Fire Pump or Pump Controller Trouble
			Fire Pump Running
			Generator in Auto Position
			Generator or Controller Trouble
			Switch Transfer
			Generator Engine Running
			Other: ____

SIGNALING LINE CIRCUITS
Quantity and style of signaling line circuits connected to system *(see NFPA 72, Table 6.6.1)*:
Quantity 2 Style(s) POTS + Cell

SYSTEM POWER SUPPLIES
(a) Primary (Main): Nominal Voltage [redacted]
Overcurrent Protection: Type ____
Location (of Primary Supply Panelbo
Disconnecting Means Location:
(b) Secondary (Standby):
Calculated capacity in
Engine-driven generator dedicated to fire alarm system?
Location of fuel storage:

TYPE BATTERY
- Dry Cell
- Lead-Acid
- Other (Specify):

[redacted]

ndby system used as a backup to primary power supply, instead of using a secondary pow
mergency system described in NFPA 70, Article 700
egally required standby described in NFPA 70, Article 701
ptional standby system described in NFPA 70, Article 702, which also meets the performance

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REMOVE STUB - SEPARATE FORMS BEFORE FILLING OUT

PRIOR TO ANY TESTING

NOTIFICATIONS ARE MADE	Yes	No	
Monitoring Entity			[redacted]
Building Occupants			
Building Management			
Other (Specify)			
AHJ Notified of Any Impairments			

SYSTEM TESTS AND INSPECTIONS

TYPE	Visual	Functional	Comments
Control Unit	✓	✓	
Interface Equipment	✓	✓	
Lamps/LEDs	✓	✓	
Fuses	✓	✓	
Primary Power Supply			
Trouble Signals	✓	✓	
Disconnect Switches			
Ground-Fault Monitoring			

SECONDARY POWER TYPE	Visual	Functional	Comments
Battery Condition	✓	✓	
Load Voltage			
Discharge Test			
Charger Test			
Specific Gravity			
TRANSIENT SUPPRESSORS			
REMOTE ANNUNCIATORS			
NOTIFICATION APPLIANCES			
Audible	✓	✓	
Visible	✓	✓	
Speakers			
Voice Clarity			

INITIATING AND SUPERVISORY DEVICE TESTS AND INSPECTIONS

[redacted]

Device Type	Visual Check	Functional Test	Factory Setting	Measured Setting	Pass	Fail
Smoke Det	✓	✓			✓	
Pull ST	✓	✓			✓	
SE Sprinkler Rm	✓	✓			✓	
Smoke	✓	✓			✓	

Comments:

EMERGENCY COMMUNICATIONS EQUIPMENT	Visual	Functional	Comments
Phone Set	✓	✓	
Phone Jacks			
Off-Hook Indicator	✓	✓	
Amplifier(s)			
Tone Generator(s)			
Call-In Signal	✓	✓	
System Performance			

COMBINATION SYSTEMS	Visual	Device Operation	Simulated Operation
Fire Extinguisher Monitoring Device/System			
Carbon Monoxide Detector/System			
(Specify)			
INTERFACE EQUIPMENT			
(Specify)			
(Specify)			
(Specify)			
SPECIAL HAZARD SYSTEMS			
(Specify)			
(Specify)			
(Specify)			

Special Procedures:

Comments:

SUPERVISING STATION MONITORING	Yes	No	Time	Comments
Alarm Signal	✓			
Alarm Restoration				
Trouble Signal	✓			
Trouble Signal Restoration				
Supervisory Signal				
Supervisory Restoration				

NOTIFICATIONS THAT TESTING IS COMPLETE	Yes	No		Time
Building Management			[redacted]	
Monitoring Agency				
Building Occupants				
Other (Specify)				

The following did not operate correctly:

System restored to normal operation: Date _____ Time: _____

THIS TEST
Name of In
Signature:
Name of O [redacted]

C Facility - Exhibit A
Page 007

Americans United for Life

Active Shooter Training 8/21/18

[redacted]

From: [redacted]
Sent: Wednesday, August 22, 2018 1:35 PM
To: [redacted]
Subject: Re: Thank you!

Good afternoon,
Thanks for completing the active assailant training on 8-21-18. If you need any other training feel free to get in touch.

Thank
[redacted]

Sent from my iPhone

On Aug 22, 2018, at 1:26 PM, [redacted] wrote:

Hi [redacted]

We just wanted to say thank you for coming to do active assailant training with us here at the Columbia Planned Parenthood. If you wouldn't mind sending us something stating we completed your training for our records, that would be great!

Thanks Again!

In Attendence

[redacted] HCN
[redacted] Lead Front office
[redacted] NP
[redacted] Temp LPN
[redacted] LPN
Grassroots Org.

[redacted]
Health Center Manager II
[redacted]

www.PPGreatPlains.org
<image001.png>

PP Great Plains works to ensure that every individual has the knowledge opportunity and freedom to make informed, private decisions about reproductive and sexual health.

<=”” img=”” src=”cid:”>

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Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 7, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

Enclosed please find the responses and plans of correction from Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP") to DHSS's statements of deficiency regarding CHPPGP's Columbia abortion facility. As part of its response, CHPPGP has included the following enclosures:

1. A signed copy of the Statement of Deficiency forms provided by DHSS. The facility administrator of CHPPGP's Columbia facility, Vicki Casey, has signed each page of the DHSS forms that appear to be largely modeled on CMS Form 2567.

2. Separate pages for each Plan of Correction and/or Objections.

CHPPGP strives to provide the highest quality care; however, many of the findings and requirements imposed by the State of Missouri and the Department of Health and Senior Services are not medically necessary and do not enhance patient outcomes. They also are, on their face, in contradiction with established United States Supreme Court precedent and are not in alignment with American College of Obstetricians and Gynecologists standards. CHPPGP notes that any agreement contained in its plans of correction to abide by federal or state laws or regulations is subject to those requirements being in force. If at any time those requirements are enjoined, modified, or otherwise rendered to have no effect, CHPPGP's plans of correction do not constitute voluntary agreement to comply with the stated requirements.

CHPPGP looks forward to working with DHSS to resolve those findings identified by the department during its recent inspection.

Sincerely,

Brie K. Anderson

Brie Anderson
Vice President for Health Services

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711
Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

October 16, 2018

Emily Wales
Chief Compliance Officer and General Counsel
Comprehensive Health of Planned Parenthood Great Plains
4402 W 109th St. #100
Overland Park, KS 66211

Dear Ms. Wales:

In accordance with 19 CSR 30-30.070(2), the Missouri Department of Health and Senior Services, Section for Health Standards and Licensure (DHSS), has approved your request to deviate from the requirements of regulation 19 CSR 30-30.070(3)(N) as set forth below for Comprehensive Health of Planned Parenthood Great Plains, 711 N. Providence Road, Columbia, MO 65203 (CHPPGP).

CHPPGP shall meet the clear space requirement of the regulation by maintaining three (3) recovery beds or recliners rather than four (4). Maintaining only three (3) recovery beds or recliners in the space available will allow space for emergency response personnel to access patients if necessary. This deviation is conditioned upon CHPPGP scheduling appointments in a manner that ensures that at no time more than three (3) patients are in simultaneous need of recovery.

This deviation shall not take effect until after CHPPGP has submitted an acceptable plan of correction for the statement of deficiencies issued September 28, 2018, and DHSS has approved the plan of correction and confirmed that such deficiencies have been corrected. The effective date of the deviation shall be the date that a license, if any, is issued. CHPPGP cannot be licensed unless it meets the hospital privileges requirement.

The deviation shall remain in effect until there is a change in circumstances, CHPPGP fails to comply with the requirements herein, or DHSS determines that there is a detrimental impact on the health, safety, or welfare of the patients, staff or public.

Abortions shall not be performed at CHPPGP until the facility is licensed and in compliance with all applicable laws, including but not limited to the hospital privileges requirement (Section 188.080, RSMo).

CHPPGP shall submit a copy of this deviation letter with its annual licensure renewal. If you have questions regarding this correspondence, please contact me at (573) 526-1864.

Sincerely,

William Koebel
Section Administrator
Section for Health Standards and Licensure

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Comprehensive Health of
Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 12, 2018

Via U.S. mail and email to: William.Koebel@health.mo.gov

William Koebel, Administrator
Section for Health Standards and Licensure
Missouri Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Re: *Request for Deviation*

Dear Mr. Koebel:

As you are aware, in 2007, the Missouri Legislature amended the Ambulatory Surgical Center Licensing Law to require any facility performing five or more first trimester abortions or one or more second trimester abortions be licensed as an ambulatory surgical center. Following that change, the Department refused to license Comprehensive Health of Planned Parenthood Great Plains' (CHPPGP) Columbia health center (as well as its Kansas City facility). After CHPPGP sued and obtained a preliminary injunction, the Department entered into a settlement agreement in 2010 by which it would license the Columbia health center to provide both medication and surgical abortion, based on CHPPGP's making certain agreed-upon changes to the health center.

Subsequent to that settlement agreement, the Department for the first time in 2015 advised CHPPGP that it would need to seek a waiver to provide abortions without having four recliners with at least three feet of clear space on both sides and at the foot of each recliner in its recovery room, as required by 19 CSR 30-30.070(3)(N). The Department did not require such waiver previously, even though the health center offered both medication and surgical abortion following the 2010 settlement agreement. CHPPGP duly applied for the waiver, and recognizing no threat to patient health or safety, the Department granted that waiver application and licensed the Columbia health center to provide medication abortion.

However, following an onsite survey conducted on October 11, 2016, the Department determined the Columbia health center was not in compliance with the above regulation because, according to the November 2, 2016 survey results, the previously approved variance did not extend to surgical abortion. The 2016 survey results also found the Columbia center was not in compliance with 19 CSR 30-30.070(3)(X), because the patient lavatory was not equipped with a constant running exhaust (despite that this same exhaust system had been approved repeatedly in the past, most recently in 2015).

As you also know, the physical facility requirements in 19 CSR 30-30.070 have been preliminarily enjoined since May 2, 2017. Given the Eighth Circuit's recent decision vacating that preliminary injunction, CHPPGP now seeks a waiver from 19 CSR 30-30.070(3)(N) for its Columbia health center, pursuant to 19 CSR 30-30.070(2). The physical standards regulation requires that the "recovery room . . . shall be of sufficient size to accommodate at least four (4) recovery beds or recliners for each procedure room. There shall be three feet (3') of clear space on both sides and at the foot of each recovery bed or recliner." 19 CSR 30-30.070(3)(N).

The Columbia facility cannot fit four recliners with at least three feet of clear space on both sides and at the foot of each recliner; it can only fit three recliners with these clearances. Creating additional space is not feasible, as it would require (a) demolishing and relocating existing walls, both of which border restroom facilities, and (b) taking square footage away from the adjoining procedure room and/or personnel change room, neither of which is permitted by the terms of the 2010 settlement agreement.

The current configuration of four recliners is appropriate to protect patient health and safety, and there would be no health or safety benefit to removing one recliner in order to allow greater clearances. The lack of an incision, general anesthesia, and deep or moderate sedation means that most patients require only minimal duration of recovery following a surgical abortion. Indeed, because the Columbia health center provides only minimal sedation (valium and a topical anesthetic) at present, patients typically require less than 20-30 minutes of recovery. Current clearances allow appropriate patient monitoring during this recovery. Indeed, during the recent inspection of the Columbia facility, on August 13 and 14, 2018, the Department did not express any concerns about the current configuration of our four recliners.

We, therefore, request a waiver of the requirement for three feet of clear space at the sides and foot of each recliner, or in the alternative, the requirement to have four recliners for each procedure room. Because of the short duration of recovery following a surgical abortion, three recliners is sufficient to meet our patients' needs. CHPPGP will resolve the exhaust fan issue by September 21, 2018.

To avoid an interruption of services, **CHPPGP respectfully requests a written response to this request by September 18**. CHPPGP is aware that the Department is unable to waive the hospital-privileges requirements and intends to seek another preliminary injunction against those provisions so that it can continue to provide services uninterrupted after the Eighth Circuit's mandate issues.

Should the Department take the position that it would need to re-inspect the Columbia facility, please advise us promptly. If the Department requires an abortion-providing physician to be present for any such inspection, our physician will be at the health center on September 17 and 21. Following September 21, CHPPGP next has abortion patients scheduled on October 3, but inspection at this time will cause a lapse in services, given that our license expires on October 2. In order to avoid such an interruption, we expect the Department to process this request, as well as our license

reapplication, in good faith and ahead of the license's expiration date, so that there is no interruption of services.

Finally, as I informed Ms. Loethen in response to your call on September 10 advising CHPPGP to cease "immediately" all abortion services because its physician does not have the required hospital privileges, CHPPGP will continue to provide abortion services to its patients, as allowed by the preliminary injunction, until the Eighth Circuit's mandate issues pursuant to the Federal Rules of Appellate Procedures, which would happen at the earliest on October 1.

I look forward to hearing your prompt response to this request.

Sincerely,

Emily Wales
Chief Compliance Officer & General Counsel

CC:

Nikki Loethen, General Counsel, Department of Health and Senior Services
D. John Sauer, First Assistant and Solicitor, Attorney General's Office

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
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Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

September 13, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains, Inc
711 N Providence Road
Columbia, MO 65203

RE: ***PoC Rejection TKOR***

Dear Vicki Casey:

On September 10, 2018 our Bureau received your Plan of Correction as a result of a Licensure Survey Survey conducted August 14, 2018. Your Plan of Correction is unacceptable as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

The facility has requested that the license not be allowed to lapse. To help ensure that, would the facility be able to implement any of the corrective actions sooner than the dates listed for tags L1084 and L1130?

L-1119 How will the facility ensure a copy of the discharge instructions will be included in the patient's medical record, consistent with current standards for medical record keeping.

L-1120 On what date does the facility expect the physician order document to be approved and implemented as the response only states in process.

L-1124 At the time of survey the state mandated reports were not included in two of the ten medical records reviewed and were not submitted to the survey team as available for the medical record. Going forward, how will the facility ensure the state mandated reports are included in the patients' medical record.

For 1130: Does the hand hygiene/glove use training include the physician?

Please submit a revised Plan of Correction with the above mentioned information within five (5) calendar days from the receipt of this notice via email to BAC@health.mo.gov or fax to (573) 751-6648 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

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September 20, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

As requested by DHSS surveyors during the re-inspection of the Kansas City facility operated by Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP"), CHPPGP has provided a number of updates and revised deadlines for the corrective action plans for its Columbia facility. Although all of CHPPGP's initial deadlines met the 45-day requirement laid out in the Department's plan of correction form (except for ongoing monitoring or audits, of course), CHPPGP has already completed many of its action items and is willing to move forward quickly to resolve any findings.

As you'll see in the attached response, all updates or revisions have been highlighted, so DHSS can easily identify where changes have been made. We anticipate that all necessary tasks – again, excluding ongoing monitoring or audit work – will be completed prior to next Friday, September 28, 2018.

We appreciate your notifying us during your Kansas City visit that revised deadlines would assist with a timely resolution of any alleged findings identified by the Department. Our goal, as always, is to provide high quality care that patients are able to access without any interruption in services.

Sincerely,

Brie Anderson
Vice President for Health Services

Americans United for Life

MO Bureau of Ambulatory Care —Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date (from CMS 2567)	8/14/2018
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	State or Federal SOD Q-tags, L-tags, K-tags, E-tags	

1. **Include a copy of the first page of each of the original forms CMS-2567** Statement(s) of Deficiencies for Federal (Q-tags, E-tags), State (L-tags) and Life Safety (K-tags) **signed & dated by administrator** or designee, along with associated completed POC forms **no later than ten (10) calendar days from receipt of this document**. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. Complete a **separate POC form for each applicable regulation set of the Statement of Deficiencies** (Federal Q-tags, E-tags, State L-tags, and Life Safety K-tags).

3. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation for Q-tags, E-tags, L-tags, and K-tags.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form CMS-2567 "Statement of Deficiencies" (Q181, L224, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date, and generally **must be** no later than 60 days from Exit. *(Limited extensions may be granted upon written request should extraordinary circumstances exist.)* To allow for adequate time for correction of deficiencies, should an onsite revisit be necessary, correction **should be completed** less than 45 days from Exit.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D." above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

Americans United for Life

MO Bureau of Ambulatory Care — Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1081	CHPPGP will conduct future drills to include both part-time ("PRN") employees and temporary contractors, if applicable, to ensure that all employees who may be on-site when CHPPGP is operating the Columbia facility are prepared for evacuation during a disaster.	8/22/2018 (actions already completed) and 10/1/2018 (additional action item) UPDATE: All action items were completed by 8/22/2018. The only outstanding item will be completed on the morning of 9/21/2018.	Health center manager and facility administrator	The manager has reviewed the current written plan for evacuation of patients and personnel in the event of a fire, explosion, active shooter or other disaster with Regional Director (facility administrator). Staff completed drills in preparation for emergencies on 8/21/2018 (active shooter training with third-party vendor) and 8/22/2018 (fire, tornado, and bomb threat) to ensure compliance. Because the active shooter training was provided by an outside party while CHPPGP's physician was not at the health center, an additional drill will be conducted while the physician is in attendance on or before October 1, 2018.	*See* Exhibit A (attached).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP will take the following steps in response to the items identified in this finding: 1. **Arrange an in-person meeting with its environmental services cleaning provider to review its expectations and standards.** Health center manager; regional director of health center operations (administrator); and vice president of operations, will attend the meeting and review with the environmental services provider each of the areas identified in DHSS's report. This step is designed to address the dust-related portions of the finding. 2. **Document on a log the daily inspection performed by personnel at the facility prior to seeing patients.** The log will be maintained for 30 days by manager and submitted to regional director for review. This step is designed to address the dust-related portions of the finding and to ensure that expired tests that are not intended for future use are disposed of in a timely manner.	Item 1 will occur within 30 days of the submission of this POC. UPDATE: An initial meeting between the manager the provider has already been conducted. Another meeting is scheduled to be completed on September 21, 2018. Item 2 will commence on 10/15/18, be evaluated daily, and conclude on 11/14/18.	Vice president of operations Manager and administrator	Item 1, a one-time meeting, will be monitored by center manager and regional director of health services operations. Item 2 will be monitored on a daily basis by manager, and on a weekly basis by regional director of health services operations (administrator).	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	3. **Administrator and VP of Operations will review with CHPPGP's facilities coordinator the following issues:** 1) Rusted areas on cabinet in observation 4; shelf in observation 5; peeling label and adhesive on chart holder and lamp, debris and stain under sink, and chipped paint in observation 6; peeling label and adhesive, debris and mark under sink, peeling on base of cabinet, chipped paint on pressed wood, and chipped laminate in observation 7; and residue under sink in observation 10. The facilities coordinator will outline a process for repair and/or replacement for those items.	UPDATE: Item 2 will commence as soon as the second meeting with the provider occurs. The meeting outlined in Item 3 will be concluded by 10/1/18, and repairs/replacements will be concluded by October 31, 2018. UPDATE: All actions outlined in Item 3 have been performed except for one outstanding repair. That work is scheduled to be completed on or before September 25, 2018.	Vice president of operations	Item 3 will be monitored by vice president for operations. In addition to scheduling the initial meeting, vice president for operations will oversee repairs and/or replacements, as necessary.	

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1090	CHPPGP objects to the deficiency in L1090, as at all times during which it operated in 2017-2018 at least one licensed employee with current CPR training was onsite, as required by regulation. CHPPGP provided to surveyors copies of CHPPGP personnel files for those employees involved in the provision of abortion care, and those files reflect current CPR training for multiple individuals.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1101	CHPPGP objects to the deficiency identified in L1101. Pursuant to state law, CHPPGP provides to patients required information at the time of their state-mandated first visit, which must occur at least 72 hours prior to the performance of an abortion procedure. CHPPGP also is required and does provide to patients Missouri's Informed Consent Booklet, which by statute must include "probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from conception to full term, including color photographs or images of the developing unborn child at two-week gestational increments." § 188.027(2), RSMo. That booklet, provided to each patient, fulfills this requirement as it outlines state-mandated descriptions of changes in gestational age from the date of a patient's first visit to her second visit. CHPPGP will ensure appropriate staff specifies during the first visit that, because of the state-mandated delay, the patient's pregnancy is anticipated to be at a certain point when she	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	returns, and the state-created description of the fetus at that future gestation is in the Missouri Informed Consent Booklet. If, for some reason, a patient needs to reschedule her appointment, the booklet will also contain the state-created description of the fetus for that later time.				

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1119	CHPPGP objects to the deficiency identified in L1119 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that each patient receiving abortion care is provided with discharge instructions that include the following hand-outs: 1) How Much Am I Bleeding? (describing post-procedure normal and abnormal bleeding); 2) medication instructions; and 3) and surgical abortion discharge instructions, which include the facility's after-hours telephone number. DHSS's report does not state, however, that an entry is made by CHPPGP personnel in each patient's medical record that the patient received copies of those documents. That entry satisfies the regulation's requirement that written discharge instructions be provided to patients.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1120	CHPPGP objects to the deficiency identified in L1120 to the extent it misstates the nature of the information conveyed during the survey process. As outlined in DHSS's findings, CHPPGP personnel informed surveyors that the physician providing care signed and dated the visit summary generated by the electronic health record, which reflects the medications prescribed during the patient encounter. To CHPPGP's knowledge, DHSS has not prior to its 2018 inspections interpreted this regulation to require each separate portion of a patient's medical record be signed and authenticated by the treating physician. As CHPPGP noted during the on-site inspection, however, it created a hard copy form in response to the inspection at its Kansas City facility. This form will provide an additional place for the physician to sign, date, and time medication orders for each patient and will be scanned into the medical record. This entry will be duplicative of that information on the patient's visit summary.	*In progress* UPDATE: The hard copy form has already been created and is in use. It was reviewed by DHSS inspectors at the re-inspection of CHPPGP's Kansas City facility.	Administrator	The form has already been developed and is in use. The center manager will review electronic health records for all patients receiving abortion care for one month after the form has been in use to monitor for compliance.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1122	CHPPGP objects to the deficiency identified in L1122 to the extent it misstates the nature of the information conveyed during the survey process. For each of the patient records reviewed by the surveyor, a physician or qualified health professional (as defined by § 188.027, RSMo) provided the state-mandated information to patients receiving abortion care. The records described in L1122 reflected that persons meeting the statutory and regulatory definitions gave the required information. CHPPGP's physician *elected* to note in a number of patient records that she had delivered state-mandated information; however, that notation was only intended to duplicate what the other records in each patient's record showed: that required personnel delivered the information. CHPPGP's physician simply went above and beyond by reiterating that she had followed state law. To the extent that notation creates confusion for DHSS, CHPPGP will note for its provider that the notation is not necessary.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.	N/A – CHPPGP objects to the finding.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1124	CHPPGP objects to the deficiency identified in L1122 *in part* to the extent it misstates the nature of the information conveyed during the survey process. At the time of inspection, two state-mandated reports, Induced Termination of Pregnancy (ITOP) reports, had already been submitted to DHSS as required but had not yet been scanned into the patients' electronic medical record. CHPPGP staff located both reports on the day of inspection, and they have since been scanned into the patients' electronic records. Additionally, CHPPGP has revised its indexing process. Administrative personnel continue to handle the submission of ITOP reports to DHSS, but the center manager now submits reports for each procedure by the close of business on the day the procedures were performed.	Completed 8/15/2018 UPDATE: The indexing process has already been revised, and the new process is in place.	Center manager and regional director (administrator)	Regional Director will be responsible for monitoring new process and verifying that all ITOP reports are submitted pursuant to revised procedure.	N/A

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (Q0001)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date (within 45-days from exit)	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1130	The director of clinical quality risk management will conduct a comprehensive training with facility staff to serve as a refresher course on CHPPGP's infection control program. CHPPGP's health center manager will also perform quarterly audits to ensure ongoing compliance after the education session.	Training will be conducted by 9/30/2018 UPDATE: A training is scheduled for 9/25/2018 at 10 a.m., and quarterly audits will be performed as outlined.	Director of clinical quality risk management and administrator	Regional director (administrator) will conduct unannounced audits after completion of training on a quarterly basis.	N/A

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments An on-site, unannounced state licensure revisit was conducted on 09/26/18 to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	{L 000}		
{L1084}	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the Abortion Facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the soiled room; - Dispose of used, soiled single-use suction tubing; - Dispose of a soiled reusable series connecting hose (clear secondary suction tubing); and - Clean and disinfect a reusable glass suction bottle. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included:	{L1084}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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{L1084}	Continued From page 1 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) should assess the perioperative environment frequently for cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components. - Recommendation III.c. * Operating and procedure rooms must be cleaned after each patient. - Recommendation V.a.1. * Areas and items that should be cleaned on a schedule include clean and soiled storage areas and sterile storage areas. 2. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - Centers for Disease Control and Prevention (CDC); - Association for Professionals in Infection Control and Epidemiology (APIC); - Association for the Advancement of Medical Instrumentation (AAMI); and	{L1084}		

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{L1084}	Continued From page 2 - AORN. 3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed: - The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment. 4. Review of the facility's "Infection Prevention Manual" policy titled, "Directions for Cleaning and Disinfection - Abortion Procedure Suction Tubing," dated 08/15, showed: - Single-use suction tubing must be disposed of as an infectious waste after each patient use. - Multi-use suction tubing is first cleaned by running water through the tube, removing all blood and bioburden immediately after the procedure. Then soak tubing in chemical disinfectant ad per manufacturer's instructions for semi-critical devices. 5. Observation on 09/26/18 at 9:40 AM of the procedure room showed: - The metal suction machine cabinet had numerous rusted areas (uncleanable surface); - There was a used, single-use suction tubing connected to a plastic suction canister. The single-use tubing contained reddish colored fluid; - A reusable series connecting hose on the top of the machine had a blackish-gray substance on the inside the length of the tubing; and - The reusable series connecting hose was connected to a reusable glass suction bottle. There was a layer of dried black substance in the bottom of the bottle. During an interview upon the observation Staff C, Health Center Manager, stated that the replacement reusable series connecting hose	{L1084}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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{L1084}	Continued From page 3 was on back order. 6. Observation on 09/26/18 at 9:50 AM of the storage room showed the metal cabinet of a second suction machine had numerous rusted areas, old peeling tape, dried adhesive residue on the front surface, (uncleanable surfaces) and a dried brown spill down the side of the machine that was approximately six-inches long. 7. During an interview on 09/26/18 at 9:55 AM, Staff C stated that: - The substance in the single-use suction tubing was most likely bodily fluid; - Their last procedure had been the previous Friday (09/21/18); - She did not think they had used the suction machine that day; and - The blackish gray substance in the secondary reusable series connecting hose was mold. 8. During an interview on 09/26/18 at 12:00 PM, Staff I, Maintenance, stated that the replacement for the reusable series connecting hose was located inside the suction machine cabinet. Staff C stated that she was not aware that the secondary replacement reusable series connecting hose was inside the suction cabinet. 9. During an interview on 09/26/18 at 2:10 PM, Staff C stated that: - She identified the problem (blackish gray residue) inside the reusable series connecting hose a couple of months previously (probably July) and began trying to find replacement tubing; - They continued to use the machine (with the reusable series connecting hose that had blackish gray residue inside) on patients after they identified the issue; and - She had talked with other people about the	{L1084}		

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{L1084}	Continued From page 4 issue with the reusable series connecting hose and it was not an infection control issue. 10. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, dated 2017, showed: - 3.3.6.4 Sterile storage: * Open or wire shelving is suitable for confined storage areas, provided that proper attention is given to traffic control, area ventilation, and housekeeping. * Storage areas should be designed to protect sterile items and their packaging from damage. - 11.1.1 Storage Facilities: * The bottom shelf of storage carts or shelving should be solid. 11. Observation on 09/26/18 at 10:00 AM of the recovery room medication supply room showed a metal storage shelving unit. There was no bottom barrier on the bottom shelf. The shelf was placed over a submersible sump pump (used to remove water that has accumulated in a water-collecting sump basin) installed in the floor. 12. Observation on 09/26/18 from 10:05 AM to 10:10 AM of exam room #1 and #2 showed each room contained a pressed wood table with chipped paint exposing the pressed wood (uncleanable surface). 13. Observation on 09/26/18 at 10:10 AM of the soiled room showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue. During an interview upon the observation, Staff C stated that housekeeping staff were responsible	{L1084}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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{L1084}	Continued From page 5 to clean and confirmed the cabinet was not clean.	{L1084}		
L1113	19 CSR 30-30.060(2)(K) The facility shall ensure, each patient prep The facility shall ensure that each patient is prepared for the abortion in a manner that facilitates her safety and comfort. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure equipment used for patient care was approved for use in healthcare facilities. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included: 1. Review of the FDA/Consumer Product Safety Commission (CPSC) document titled, "FDA/CPSC Public Health Advisory - Hazards Associated with the Use of Electric Heating Pads", dated 12/12/95, showed: - The FDA and CPSC have received many reports of injury and death from burns, electric shock and fires associated with the use of electric heating pads. - An electric heating pad can be dangerous for patients with decreased temperature sensation and patients taking medication for pain. - Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting. FDA and CPSC recommend the following precautions be taken to avoid hazards associated with the use of electric heating pads:	L1113		

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L1113	Continued From page 6 - Never [partial list]: * Use on a person who has skin that is not sensitive to temperature changes (e.g. sedated or medicated for pain). * Use in an oxygen enriched environment or near equipment that stores or emits oxygen. 2. Observation 09/26/18 at 9:30 AM in the recovery room showed: - Four recovery chairs with heating pads draped across the backs. - Three of the four heating pads were labeled "For Household Use Only" and the fourth heating pad was not labeled. - The fourth heating pad cover showed a one inch streak of clear, hard surface matter with a small circular bead of clear material at the top on the heating pad cover. 3. During an interview on 09/26/18 at 1:45 PM, Staff C, Health Center Manager, stated that: - The heating pads were for household use and needed to be removed. - She did not believe the facility had a policy for the use of heating pads.	L1113		

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Comprehensive Health of
Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 28, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

As requested by DHSS surveyors during the re-inspection of the Columbia facility operated by Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP"), CHPPGP has enclosed with this letter a number of items documenting compliance with its plan of correction. I believe you spoke with a maintenance employee while he performed work on CHPPGP's two suction machines on September 26; however, we wanted to include photographs of his finished work for your review. We have also included the final sign-in sheet for the hand-washing refresher course provided by CHPPGP's director of compliance and quality risk management.

I also wanted to provide you with an update on the timing of delivery for the new desks. It was my understanding during the first inspection that evidence of the receipt of purchase was sufficient for inspection purposes, and we produced the receipt that day. At the Department's request, shortened the internal timelines for completing many items on our plan of correction; however, we are unable to shorten the delivery time for the desks. We still anticipate that they will be delivered any day, but it's our understanding that Hurricane Florence has caused some delay. We intend to call the vendor today to check on timing and will produce pictures of the desks once delivered.

Additionally, although we have not yet received the revised statement of deficiencies, we have ordered four new medical-grade heating pads and a splash guard for the bottom shelf of the closet shelving unit, as discussed during your visit. Copies of those receipts are enclosed.

As you know, we are eager to resolve any outstanding issues to ensure that we receive our license in a timely manner and are not forced to have an interruption in services for our patients. We appreciated hearing from you on Wednesday that you plan to expedite any follow-up plan of correction in an effort to proceed as quickly as possible.

Sincerely,

Vicki Casey
Regional Director for Health Center Operations
Facility Administrator

Enclosures: Photographs of suction machines (Serial Nos. 11310 and 2M1917)
Hand-washing course sign-in sheet
Receipts for heating pads and shelf guard

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In-Service Documentation

Location: Columbia
Manager: [redacted]
Date of Training: 9/27/18
Length of Training: 20 min
Title/Topic: Infection Prevention - Hand Washing
Name of Presenter: [redacted]
Presenting Agency: PPGP

STAFF IN ATTENDANCE

Printed Name	Signature
[redacted] NP	[redacted]
[redacted]	
[redacted] NP	
Note: Both nurse practitioners, a licensed practical nurse, the health center manager, and the regional director of health center operations completed the training. A separate sheet reflecting the physician's participation was previously produced to surveyors.	

Managers should complete this form for all required and optional in-service trainings, asking each staff member in attendance to print and sign their names. Attach any additional required pieces of training documentation and submit a copy to the Human Resources Department.

Americans United for Life

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Planned Parenthood Great Plains

In-Service Documentation

Location: Columbia Manager: Angela Huntington
Date of Training: 9/27/18 Length of Training: 20 min
Title/Topic: Infection Prevention - Hand Washing
Name of Presenter: Janet Smith
Presenting Agency: PPGP

STAFF IN ATTENDANCE

Printed Name	Signature
Angela Huntington	
Mary Pat Risinger, NP	
Nicole O'Bryan	
Kristin Metcalf-Wilson, NP	
Vicki Casey	

Managers should complete this form for all required and optional in-service trainings, asking each staff member in attendance to print and sign their names. Attach any additional required pieces of training documentation and submit a copy to the Human Resources Department.

Americans United for Life

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

CHPPGP aspiration machine
Serial No. 11310

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

CHPPGP suction machine
Serial No. 2M1917

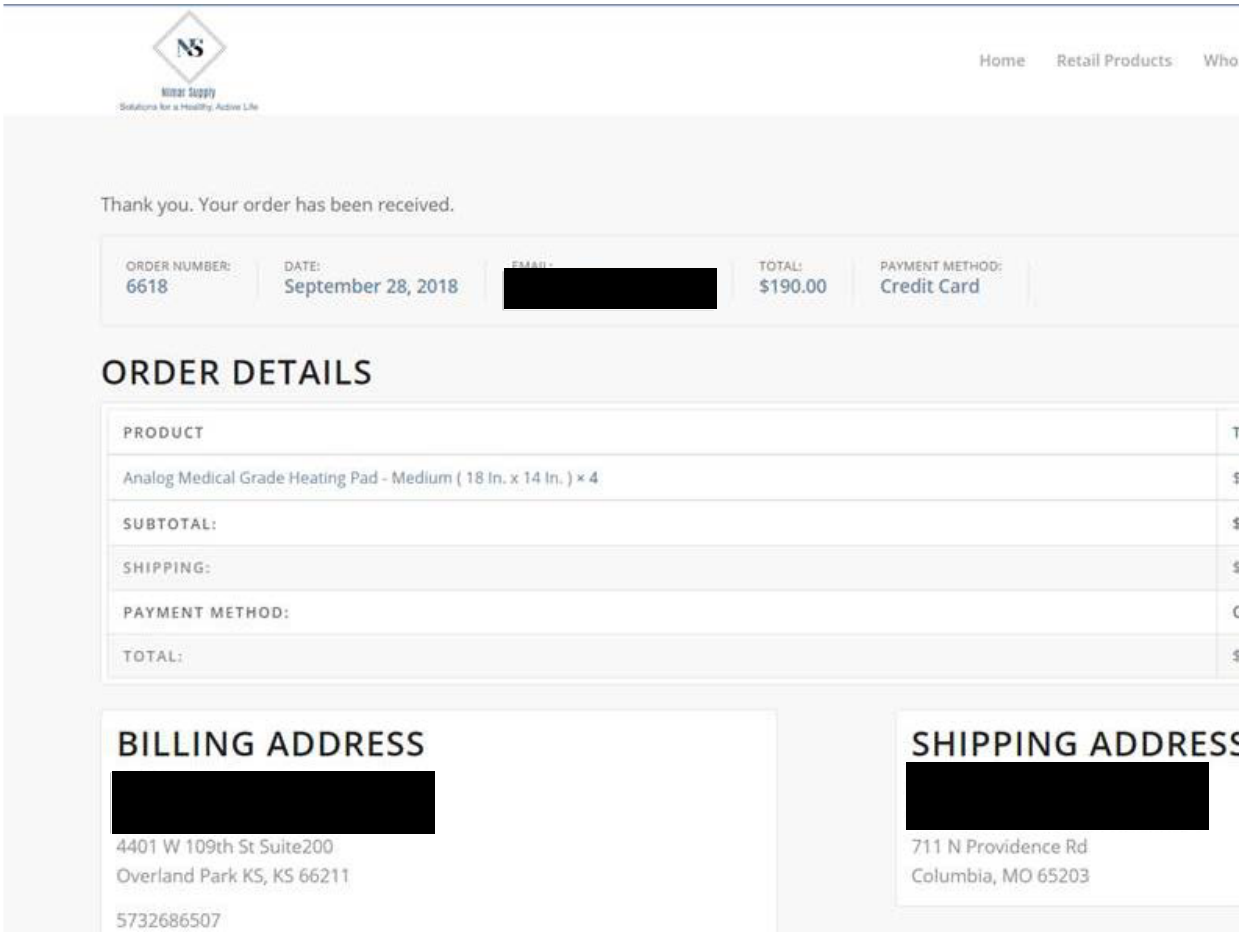
CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

[redacted]
[redacted]

Subject: Heating Pads
Date: Friday, September 28, 2018 1:34:15 PM



NS
Home Retail Products Who

Thank you. Your order has been received.

ORDER NUMBER:	DATE:	EMAIL:	TOTAL:	PAYMENT METHOD:
6618	September 28, 2018	[redacted]	$190.00	Credit Card

ORDER DETAILS

PRODUCT	
Analog Medical Grade Heating Pad - Medium (18 In. x 14 In.) × 4	
SUBTOTAL:	
SHIPPING:	
PAYMENT METHOD:	
TOTAL:	

BILLING ADDRESS

[redacted]
4401 W 109th St Suite200
Overland Park KS, KS 66211

5732686507

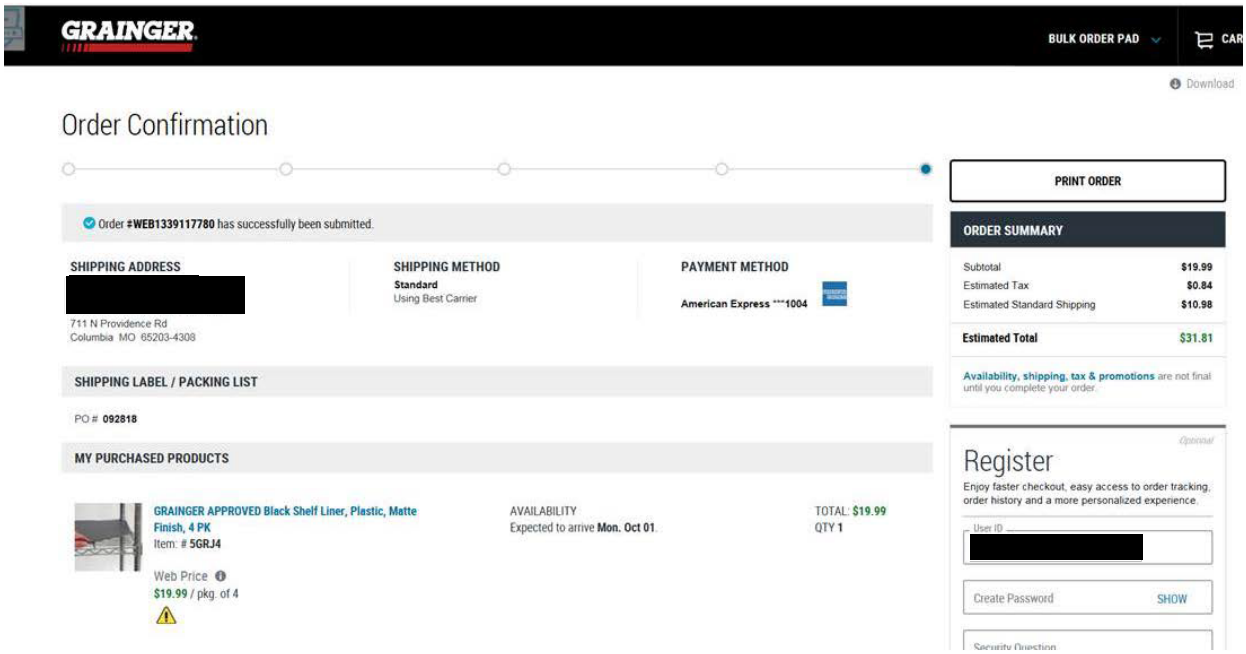
SHIPPING ADDRESS

[redacted]
711 N Providence Rd
Columbia, MO 65203

Americans United for Life

[redacted]

[redacted]
Sent: Friday, September 28, 2018 1:20 PM
[redacted]
Subject: Shelf Guard



[redacted]
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
[redacted]

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September 29, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

Enclosed please find CHPPGP's second plan of correction, which corresponds with the statement of deficiencies we received from your office yesterday afternoon.

I am pleased to note that all of the issues identified had been addressed prior to our receipt of the statement. As you know, however, there are a number of items we have purchased but not yet received, including the side tables and heating pads.

We include with this plan of correction only one exhibit: the same information we submitted to the Department yesterday prior to our receipt of the statement.

Thank you in advance for your prompt review of our plan. We look forward to resolving any outstanding issues.

Sincerely,

Vicki Casey
Regional Director for Health Center Operations
Facility Administrator

Enclosures: Second Plan of Correction
Signed Statement of Deficiencies
September 28, 2018 CHPPGP letter to DHSS and attachments

Americans United for Life

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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{L 000}	Initial Comments An on-site, unannounced state licensure revisit was conducted on 09/26/18 to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	{L 000}		
{L1084}	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the Abortion Facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the soiled room; - Dispose of used, soiled single-use suction tubing; - Dispose of a soiled reusable series connecting hose (clear secondary suction tubing); and - Clean and disinfect a reusable glass suction bottle. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included:	{L1084}		

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date	8/14/2018 (first survey) 9/26/2018 (second survey)
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	Statement of Deficiencies (SOD): L-tags	L1084; L1113

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc).

   B. (CORRECTIVE ACTION):
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. (WHEN):
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. (WHO):
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. (MONITORING AND/OR TRACKING PROCEDURES):
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. EVIDENCE/EXHIBIT ATTACHMENTS(s). If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

Americans United for Life

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP objects to the deficiency identified in L1084 to the extent it misstates the nature of the information conveyed during the survey process. CHPPGP offers the following responses: 1. Suction machine cabinet: As outlined in CHPPGP's initial plan of correction, CHPPGP's facilities coordinator planned to perform maintenance on the cabinet by October 31, 2018. Because DHSS performed its inspection in close proximity to the expiration date of CHPPGP's license, CHPPGP agreed to DHSS's request that it shorten its timeline to ensure the task would be completed prior to Oct. 2. The maintenance was performed on September 26 as DHSS surveyors observed, and pictures have already been produced to DHSS reflecting the maintenance.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	2. Single-use suction tubing: CHPPGP disposed of the tubing on the date of the survey, and pictures have already been produced to DHSS reflecting resolution.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).
	3. Connecting hose: CHPPGP's facilities coordinator replaced the hose on the date of the survey (as state surveyors observed) and identified the discoloration as dust or dirt. He did not identify mold and, importantly, DHSS performed no tests that could have identified mold. Any conclusions drawn by surveyors were therefore speculative. CHPPGP notes that there are multiple inaccuracies contained within the statement of deficiencies regarding the connecting hose. DHSS wrongly states that CHPPGP personnel described the hose as having "mold." The staff person did not agree with surveyors that there was mold and instead stated that she did not know what the substance was. Additionally, staff had worked to locate a replacement hose and did not believe the one they had ordered and placed in the machine's cabinet fit the machine. The facilities coordinator was able to use that	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	replacement piece, however, and the maintenance is now complete. The machine was used for only two procedures between July and September 2018. At all times CHPPGP and its personnel used aseptic non-touch technique and ensured that any instruments coming into contact with the uterus were sterile.				
	4. Suction bottle: The machine's bottles have been replaced by plastic canisters, as shown in the pictures already produced to DHSS. Additionally, CHPPGP notes that the bottle was part of the suction function of the machine and was not connected to any equipment that came into contact with patients.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 1).
	5. Secondary suction machine: Maintenance has been performed on the machine, which was not in use, and any issues identified have been resolved. Pictures have already been produced to DHSS.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (photos of Suction Machine No. 2).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	6. Storage shelf: At DHSS's request, CHPPGP replaced the shelving unit in its supply room with a metal unit. It has since ordered a shelf guard for the lowest shelf and previously produced the receipt of purchase to DHSS. According to the vendor, delivery is anticipated on Monday, October 1.	Shelf guard ordered prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (copy of shelf guard receipt).
	7. Tables: CHPPGP had ordered replacement tables (on which staff take notes) prior to DHSS's second survey on September 26; however, it is CHPPGP's understanding that delivery has been delayed due to Hurricane Florence. CHPPGP previously produced the receipt of purchase to DHSS.	Tables ordered prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (copy of tables receipt).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	8. Soiled room sink: As discussed with surveyors on the date of their visit, the residue was caused by detergent and was removed on the date of the visit. Additionally, CHPPGP discussed in great detail with surveyors during the visit that it had conducted multiple meetings with its environmental services cleaning provider to review expectations and planned to begin performing additional daily inspections to assess the provider's work.	Completed prior to receipt of statement of deficiencies.	VP of Operations	The VP of Operations will continue to oversee regular repairs and/or maintenance.	*See* Exhibit A (copy of tables receipt).
L1113	CHPPGP has already ordered four medical-grade heating pads for its recovery room. It previously produced the receipt of purchase to DHSS. Because the pads are for patient comfort in the recovery room and are not medically necessary, CHPPGP will remove the pads from use until the new pads are received.	Completed prior to receipt of statement of deficiencies.	Health Center Manager	The facility's Health Center Manager will ensure the new heating pads are used.	*See* Exhibit A (copy of heating pads receipt).

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September 28, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

As requested by DHSS surveyors during the re-inspection of the Columbia facility operated by Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP"), CHPPGP has enclosed with this letter a number of items documenting compliance with its plan of correction. I believe you spoke with a maintenance employee while he performed work on CHPPGP's two suction machines on September 26; however, we wanted to include photographs of his finished work for your review. We have also included the final sign-in sheet for the hand-washing refresher course provided by CHPPGP's director of compliance and quality risk management.

I also wanted to provide you with an update on the timing of delivery for the new desks. It was my understanding during the first inspection that evidence of the receipt of purchase was sufficient for inspection purposes, and we produced the receipt that day. At the Department's request, shortened the internal timelines for completing many items on our plan of correction; however, we are unable to shorten the delivery time for the desks. We still anticipate that they will be delivered any day, but it's our understanding that Hurricane Florence has caused some delay. We intend to call the vendor today to check on timing and will produce pictures of the desks once delivered.

Additionally, although we have not yet received the revised statement of deficiencies, we have ordered four new medical-grade heating pads and a splash guard for the bottom shelf of the closet shelving unit, as discussed during your visit. Copies of those receipts are enclosed.

As you know, we are eager to resolve any outstanding issues to ensure that we receive our license in a timely manner and are not forced to have an interruption in services for our patients. We appreciated hearing from you on Wednesday that you plan to expedite any follow-up plan of correction in an effort to proceed as quickly as possible.

Sincerely,

Vicki Casey
Regional Director for Health Center Operations
Facility Administrator

Enclosures: Photographs of suction machines (Serial Nos. 11310 and 2M1917)
Hand-washing course sign-in sheet
Receipts for heating pads and shelf guard

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In-Service Documentation

Location: Columbia
Manager: [redacted]
Date of Training: 9/27/18
Length of Training: 20 min
Title/Topic: Infection Prevention - Hand Washing
Name of Presenter: [redacted]
Presenting Agency: PPGP

STAFF IN ATTENDANCE

Printed Name	Signature
[redacted] NP	[redacted]
[redacted]	
Note: Both nurse practitioners, a licensed practical nurse, the health center manager, and the regional director of health center operations completed the training. A separate sheet reflecting the physician's participation was previously produced to surveyors.	

Managers should complete this form for all required and optional in-service trainings, asking each staff member in attendance to print and sign their names. Attach any additional required pieces of training documentation and submit a copy to the Human Resources Department.

Americans United for Life

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

CHPPGP aspiration machine
Serial No. 11310

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CHPPGP aspiration machine
Serial No. 11310

CHPPGP Second Plan of Correction
Exhibit A - Page 007

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

[redacted]
[redacted]

Subject: Heating Pads
Date: Friday, September 28, 2018 1:34:15 PM

NS
Home Supply

Home Retail Products Who

Thank you. Your order has been received.

ORDER NUMBER:	DATE:	EMAIL:	TOTAL:	PAYMENT METHOD:
6618	September 28, 2018	[redacted]	$190.00	Credit Card

ORDER DETAILS

PRODUCT	
Analog Medical Grade Heating Pad - Medium (18 In. x 14 In.) × 4	
SUBTOTAL:	
SHIPPING:	
PAYMENT METHOD:	
TOTAL:	

BILLING ADDRESS

[redacted]
4401 W 109th St Suite200
Overland Park KS, KS 66211

5732686507

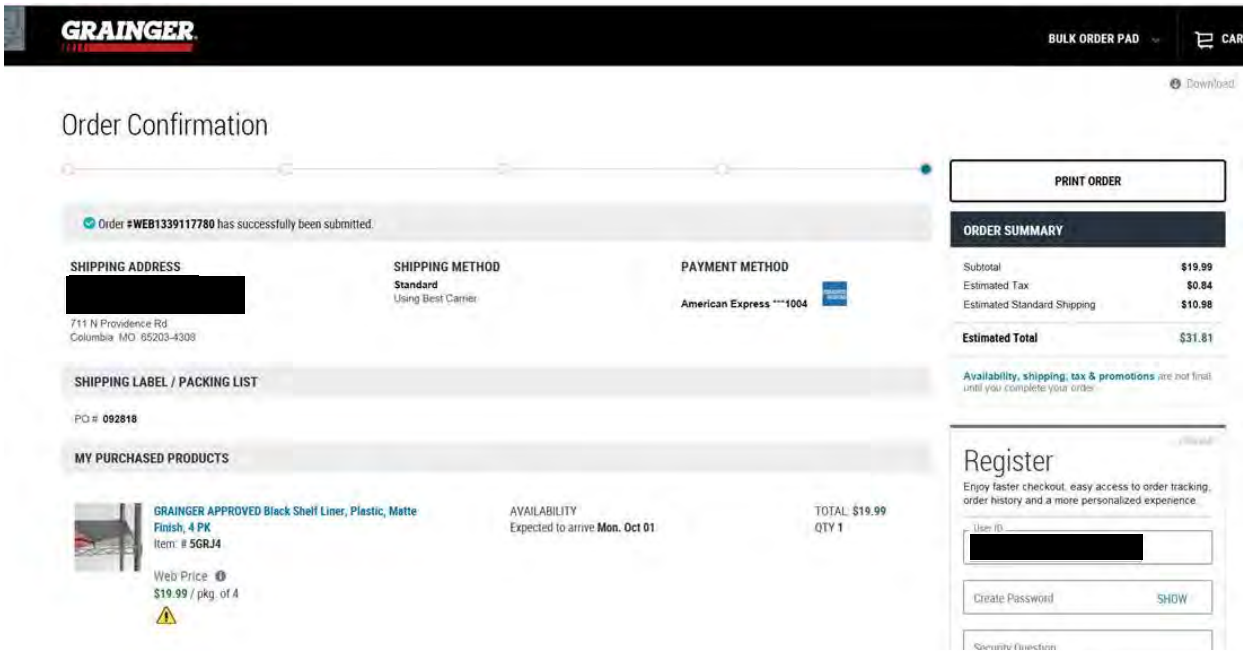
SHIPPING ADDRESS

[redacted]
711 N Providence Rd
Columbia, MO 65203

Americans United for Life

[redacted]

[redacted]
Sent: Friday, September 28, 2018 1:20 PM
[redacted]
Subject: Shelf Guard



[redacted]
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
[redacted]

Americans United for Life

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

October 16, 2018

Vicki Casey
Comprehensive Health of Planned Parenthood Great Plains, Inc.
711 N Providence Road
Columbia, MO 65203

RE: ***PoC Rejection***

Dear Vicki Casey:

On September 29, 2018 our Bureau received your Plan of Correction as a result of a Licensure revisit inspection conducted on September 26, 2018. Your Plan of Correction is **unacceptable** as submitted. The following issues need additional clarification and/or information in order for the Plan of Correction to be acceptable. These areas are as follows:

In reference to the deficiency identified in ***L-1084-*** The Plan of Correction fails to indicate the date the correction will be fully implemented for each example. Further, the Plan of Correction fails to identify the systemic changes that will be implemented to ensure that the deficient practice will not recur. The description must be specific, realistic and complete.

Additionally, please provide information regarding any and all efforts made by your agency since August 14, 2018, to notify abortion patients of their potential exposure to an infection control risk.

Please submit a revised Plan of Correction with the above mentioned information as soon as possible via email to BAC@health.mo.gov or fax to (573) 751-6648 or mail to Missouri Department of Health and Senior Services, Bureau of Ambulatory Care, P.O. Box 570, Jefferson City, MO 65102-0570. I have attached a detailed instruction sheet for your reference.

We welcome any questions at 573-751-1588.

Respectfully,

Todd Cummins, Assistant Administrator
Bureau of Ambulatory Care
Missouri Department of Health & Senior Services

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name		Survey Exit Date	
Facility Address/ City/Zip		Statement of Deficiencies (SOD): L-tags	

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction. Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. **(TAG):**
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc).

   B. **(CORRECTIVE ACTION):**
   Fully describe the plan for correcting the deficiency. Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable. The POC should be a **standalone document**, giving sufficient detail to show compliance. Do not attach policies, meeting minutes, or training documentation unless necessary and only include the pertinent sections to answer the deficiency. These documents must be available to the survey team at the revisit. However, it is acceptable to reference a policy as needed describing only what is pertinent to the POC. The POC may provide a brief description of training documentation or meeting minutes to demonstrate compliance.

   C. **(WHEN):**
   For each deficiency, indicate **date correction will be made** on all components for correction put in place. Correction CANNOT be prior to the Exit Date.

   D. **(WHO):**
   Refer to the one person responsible for implementing the plan of correction for each deficiency by **job title** only and not proper names.

   E. **(MONITORING AND/OR TRACKING PROCEDURES):**
   Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. These monitoring/tracking activities should begin soon after exit and may continue for an extended period of time past the correction date to ensure ongoing compliance. If the person responsible for ongoing monitoring is different than the person named in "D," above then note it here. If you choose to use percentages to describe evidence of compliance, use only 100%. It is acceptable to state "until compliance is achieved" rather than percentages."

   F. **EVIDENCE/EXHIBIT ATTACHMENTS(s).** If written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A"

MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number (L1128)	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"

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October 30, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via email to Todd.Cummins@health.mo.gov, William.Koebel@health.mo.gov, and BAC@health.mo.gov

Dear Mr. Cummins,

Enclosed please find CHPPGP's revisions to its second plan of correction, which add additional information to our prior submission.

Revised Plan of Correction

While your letter dated October 16, 2018 states that CHPPHP's September 29 Plan of Correction "fails to indicate the date the correction will be fully implemented for each example," CHPPGP has repeatedly contacted DHSS – before and after receiving the revised statement of deficiencies – to ensure the Department was aware that we had already taken steps to address issues raised by DHSS, as demonstrated by multiple emails and photos sent to your office. Additionally, CHPPGP had already purchased prior to submitting the September 29 plan of correction, items at DHSS's request that were not raised in the first statement of deficiencies. CHPPGP produced receipts at the time of purchase and subsequently provided photos to your office when those items were received on October 1 (via email to former General Counsel Nikki Loethen) and October 3 (via email to you and Mr. Koebel) to confirm with DHSS that they were in place.

Specific steps regarding ongoing monitoring and inspection of the procedure room and its equipment have been included in this revised plan. New or revised sections of the amended plan are in **blue**.

Notification

Your October 16 letter also asked for information regarding notification to abortion patients of a potential exposure to an infection control risk since August 14, 2018. For the reasons laid out in CHPPGP's September 29 Plan of Correction, CHPPGP believes there has been no patient exposure to an infection control risk, and certainly none that would make a patient notification appropriate under applicable guidelines. However, CHPPGP's highest priority is to ensure patient access to care in Columbia, and as DHSS is well-aware, because CHPPGP cannot currently provide abortions in Columbia women are being forced to travel hundreds of miles to access care. For that reason, as set forth more fully below, in the interest of resolving this licensing issue CHPPGP has provided the requested patient notification to the single patient in whose procedure the suction machine was used after August 14, 2018.

CHPPGP's director of compliance and quality risk management (CQRM) has analyzed guidelines produced by the Centers for Disease Control and Prevention (CDC) to determine whether any patient notification is appropriate regarding the connecting tube on the suction machine. The CDC guidance focuses on risks of potential *bloodborne pathogen transmission*, which is not at issue here. Even

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when analyzing the risk of bloodborne pathogens, such as Hepatits B or HIV, the CDC recognizes that not all potential risks are alike, and the appropriateness of patient notification depends on the type of potential breach. The CDC outlines two categories of potential breaches: 1) Category A, which includes breaches for which the assessed risk includes "documented bloodborne pathogen transmission in association with similar practices in the past, or the observed or very high likelihood of blood exposure as a result of the breach"; and 2) Category B, breaches "where the likelihood of blood exposure . . . is uncertain, but thought to be less than would occur with a Category A breach."[1] An example of a Category A breach includes the reuse of needles or syringes between patients, which is wholly dissimilar to CHPPGP's situation. A Category B example – colonoscope reprocessing performed with incorrect disinfectant solutions – is more comparable to the tubing issue; however, it too focuses on potential bloodborne pathogen transmission from equipment that *enters the body*, which is significantly different than the facts here, where the tube makes no contact with a patient.

In the instance of a Category B breach, "the decision to notify and/or test patients should be based on a number of factors including the information gathered and assessment of the breach and should involve key stakeholders." The CDC further notes that for category B breaches, the duty to notify should be weighed against potential harm from notification.[2]

Nevertheless, in an abundance of caution and given the critical importance of swiftly bringing this license renewal process to a close to ensure CHPPGP can provide abortion services in Columbia to patients who need them, on October 24 CHPPGP notified the one patient whose procedure involved the suction machine after August 14, 2018 by both telephone and the attached letter of the tube-related incident. The patient confirmed she has had no post-procedure complications or concerns.

We look forward to hearing from you soon to complete the licensure process.

Sincerely,

Brie Anderson
Vice President of Health Services

Enclosures: Revised Second Plan of Correction and Exhibits A–D
Redacted Patient Notification Letter

Americans United for Life

[1] Centers for Disease Control & Prevention, Steps for Evaluating an Infection Control Breach, *available at* https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html.
[2] *Id.*

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October 24, 2018

[redacted]

Dear [redacted]:

I am contacting you to follow up on our conversation on October 24, 2018 regarding your care at Comprehensive Health of Planned Parenthood Great Plains (CHPPGP) in September 2018.

As discussed during that call, the Missouri Department of Health and Senior Services has requested that we notify you of a potential exposure relating to medical equipment we used during your care. The Department raised concerns after a recent inspection that a tube in the machine, which does not come into contact with the patient, was discolored. The source of the discoloration was not identified. The tubing in the machine had been cleaned, and we believe the machine and tube were safe for use. We have decided to replace the tube periodically so it will not become discolored again.

Our first priority is high quality patient care, and we apologize for any concern this issue may cause. Please contact me if you have any questions or need additional information:

[redacted] RN MSN CPHQ
Director of Compliance and Quality Risk Management
Phone: [redacted]
Email: [redacted]@PPGreatPlains.org

Again, thank you for speaking with me today. I was pleased to hear that you have not experienced any complications or concerns since your appointment with us, and I hope that you will consider CHPPGP for your future health care needs.

Sincerely,

[redacted]
Director of Compliance & Quality Risk Management

MO Bureau of Ambulatory Care —Ab Facility Plan of Correction (POC) Instructions

Facility Name	Comprehensive Health of Planned Parenthood Great Plains, Inc. – Columbia Health Center	Survey Exit Date	8/14/2018 (first survey) 9/26/2018 (second survey) **10/16/2018 (third POC requested by DHSS)**
Facility Address/ City/Zip	711 N Providence Road, Columbia, MO 65203	Statement of Deficiencies (SOD): L-tags	L1084; L1113

1. **Include a copy of the first page of the original Statement(s) of Deficiencies** for the State (L-tags) **signed & dated by administrator** or designee, along with associated completed POC forms. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-1588.

2. **Required elements of an acceptable Plan of Correction**. **Each** deficiency shall be addressed separately by completing the applicable information for **all** elements below for **every** citation.

   A. (TAG):
   Indicate the prefix or Tag number for each deficiency indicated on the form Statement of Deficiencies (L1128, L1136, etc).

   B. (CORRECTIVE ACTION):
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MO Bureau of Ambulatory Care — Ab Facility Plan of Correction (POC) Form

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ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
L1084	CHPPGP objects to the deficiency identified in L1084 to the extent it misstates the nature of the information conveyed during the survey process. CHPPGP offers the following responses: 1. Suction machine cabinet: As outlined in CHPPGP's initial plan of correction, CHPPGP's facilities coordinator planned to perform maintenance on the cabinet by October 31, 2018. Because DHSS performed its inspection in close proximity to the expiration date of CHPPGP's license, CHPPGP agreed to DHSS's request that it shorten its timeline to ensure the task would be completed prior to Oct. 2. The maintenance was performed on September 26 as DHSS surveyors observed, and pictures have already been produced to DHSS reflecting the maintenance.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	VP of Operations, Health Center Manager, Administrator/Regional Director of Health Services, Director of Compliance and Quality Risk Management	As to items 1-5 of L1084 CHPPGP has created a checklist list of post-procedure items to ensure that health center staff complete all necessary tasks between procedures. The list, which is attached as Exhibit B, outlines steps to be performed by an assigned staff member (the assisting nurse or her designee) and includes a visual inspection of the suction machine, removal and disposal of single-use tubing, cleaning of connecting tubing pursuant to the infection prevention manual, and changing of plastic canisters. These items will apply to CHPPGP's secondary suction machine when it is in use as well.	*See* Exhibit A (photos of Suction Machine No. 1) and Exhibit B (post-procedure checklist).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	2. Single-use suction tubing: CHPPGP disposed of the tubing on the date of the survey, and pictures have already been produced to DHSS reflecting resolution.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	The assisting nurse or her designee will dispose of the tube after each use, and the Center Manager and Regional Director will provide oversight as described in Column E.	CHPPGP will complete and maintain checklists for the six months following the renewal of its license to allow for oversight and review. In addition to the Center Manager completing a review of the day's checklist at the end of each day on which CHPPGP offers abortion care, the Manager will submit the checklists for approval to the Regional Director for the six-month period after CHPPGP obtains its renewed license and begins offering abortion services. The Regional Director will review and confirm the checklist has been completed and will perform periodic, unannounced visual inspections of both the primary and secondary suction machines. The Director of Compliance and Quality Risk Management will also conduct a training prior to November 9, 2018 with CHPPGP employees in Columbia to review	*See* Exhibits A and B.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	3. Connecting hose: CHPPGP's facilities coordinator replaced the hose on the date of the survey (as state surveyors observed) and identified the discoloration as dust or dirt. He did not identify mold and, importantly, DHSS performed no tests that could have identified mold. Any conclusions drawn by surveyors were therefore speculative. CHPPGP notes that there are multiple inaccuracies contained within the statement of deficiencies regarding the connecting hose. DHSS wrongly states that CHPPGP personnel described the hose as having "mold." The staff person did not agree with surveyors that there was mold and instead stated that she did not know what the substance was. Additionally, staff had worked to locate a replacement hose and did not believe the one they had ordered and	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	The assisting nurse or her designee will clean the tube at the end of each procedure day, and the Center Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.	the cleaning procedures for both suction machines. She will also conduct an annual survey inspection, which includes a visual inspection of the machines. As before, the VP of Operations will continue to oversee regular repairs and/or maintenance, including the ordering of replacement parts for the suction machines.	*See* Exhibits A and B.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	placed in the machine's cabinet fit the machine. The facilities coordinator was able to use that replacement piece, however, and the maintenance is now complete. The machine was used for only two procedures between July and September 2018. At all times CHPPGP and its personnel used aseptic non-touch technique and ensured that any instruments coming into contact with the uterus were sterile. 4. Suction bottle: The machine's bottles have been replaced by plastic canisters, as shown in the pictures already produced to DHSS. Additionally, CHPPGP notes that the bottle was part of the suction function of the machine and was not connected to any equipment that came into contact with patients.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	The assisting nurse or her designee will change the bottles after each use, and the Center Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.		*See* Exhibits A and B.

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	5. Secondary suction machine: Maintenance has been performed on the machine, which was not in use, and any issues identified have been resolved. Pictures have already been produced to DHSS.	Completed prior to receipt of statement of deficiencies. Maintenance performed on 9/26/2018 and photos produced to DHSS on 9/28/2018.	Assigned staff will perform required tasks between procedures and the Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.		*See* Exhibits A and B.
	6. Storage shelf: At DHSS's request, CHPPGP replaced the shelving unit in its supply room with a metal unit. It has since ordered a shelf guard for the lowest shelf and previously produced the receipt of purchase to DHSS. According to the vendor, delivery is anticipated on Monday, October 1.	Shelf guard ordered prior to receipt of statement of deficiencies. Installed (and DHSS notified) on 10/1/2018.	Assigned staff will perform required tasks between procedures. Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by facilities coordinator.	The Health Center Manager will include inspection of the shelf guard (and cleaning of the guard, as necessary) as part of her daily monitoring of the performance of the environmental cleaning service provider.	*See* Exhibit A (copy of shelf receipt) and Exhibit D (October 3, 2018 email to DHSS).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	7. Tables: CHPPGP had ordered replacement tables (on which staff take notes) prior to DHSS's second survey on September 26; however, it is CHPPGP's understanding that delivery has been delayed due to Hurricane Florence. CHPPGP previously produced the receipt of purchase to DHSS.	Tables ordered prior to receipt of statement of deficiencies. New tables installed (and DHSS notified) on 10/3/2018.	Assigned staff will perform all required tasks between procedures and the Center Manager and Regional Director will provide oversight as described in Column E. Maintenance will be performed by the facilities coordinator.	The Health Center Manager will include inspection of the new tables as part of her daily monitoring of the performance of the environmental cleaning service provider.	*See* Exhibit A (copy of tables receipt) and Exhibit C (October 1, 2018 email to DHSS).

A (TAG)	B (CORRECTIVE ACTION)	C (WHEN)	D (WHO)	E (EVIDENCE OF COMPLIANCE)	F
ID/tag number	Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice.	Correction Date	Title of Person Responsible for Correction. No names	Describe monitoring procedure to ensure continued compliance, to include: - Frequency/duration of monitoring - Method of data collection - Who monitors, if different than "**D**"	Evidence/ Exhibit Attachment Numbers or "N/A"
	8. Soiled room sink: As discussed with surveyors on the date of their visit, the residue was caused by detergent and was removed on the date of the visit. Additionally, CHPPGP discussed in great detail with surveyors that it had conducted multiple meetings with its environmental services cleaning provider to review expectations and planned to begin performing additional daily inspections to assess the provider's work.	Completed prior to receipt of statement of deficiencies. Sink cleaned 9/26/2018. Second meeting with environmental cleaning on 9/26/2018.	VP of Operations and Health Center Manager	The Health Center Manager will include inspection of the sink as part of her daily monitoring of the performance of the environmental cleaning service provider. The VP of Operations will continue to provide oversight of cleaning service provider performance.	
L1113	CHPPGP has already ordered four medical-grade heating pads for its recovery room. It previously produced the receipt of purchase to DHSS. Because the pads are for patient comfort in the recovery room and are not medically necessary, CHPPGP will remove the pads from use until the new pads are received.	Completed prior to receipt of statement of deficiencies. Medical-grade pads received (and photos sent to DHSS) on 10/3/2018.	Health Center Manager	The facility's Health Center Manager will ensure the new heating pads are used.	*See* Exhibit A (copy of heating pads receipt) and Exhibit D (October 3, 2018 email to DHSS).

Planned Parenthood
Care. No matter what.
Comprehensive Health of
Planned Parenthood Great Plains

4402 W 109th St. #100
Overland Park, KS 66211
p: (913) 345-1400
www.ppgreatplains.org

September 28, 2018

Todd Cummins
Bureau of Ambulatory Care
Department of Health and Senior Services
P.O. Box 570
Jefferson City, MO 65102-0570

Via U.S. Mail and email to Todd.Cummins@health.mo.gov and BAC@health.mo.gov

Dear Mr. Cummins,

As requested by DHSS surveyors during the re-inspection of the Columbia facility operated by Comprehensive Health of Planned Parenthood Great Plains, Inc. ("CHPPGP"), CHPPGP has enclosed with this letter a number of items documenting compliance with its plan of correction. I believe you spoke with a maintenance employee while he performed work on CHPPGP's two suction machines on September 26; however, we wanted to include photographs of his finished work for your review. We have also included the final sign-in sheet for the hand-washing refresher course provided by CHPPGP's director of compliance and quality risk management.

I also wanted to provide you with an update on the timing of delivery for the new desks. It was my understanding during the first inspection that evidence of the receipt of purchase was sufficient for inspection purposes, and we produced the receipt that day. At the Department's request, shortened the internal timelines for completing many items on our plan of correction; however, we are unable to shorten the delivery time for the desks. We still anticipate that they will be delivered any day, but it's our understanding that Hurricane Florence has caused some delay. We intend to call the vendor today to check on timing and will produce pictures of the desks once delivered.

Additionally, although we have not yet received the revised statement of deficiencies, we have ordered four new medical-grade heating pads and a splash guard for the bottom shelf of the closet shelving unit, as discussed during your visit. Copies of those receipts are enclosed.

As you know, we are eager to resolve any outstanding issues to ensure that we receive our license in a timely manner and are not forced to have an interruption in services for our patients. We appreciated hearing from you on Wednesday that you plan to expedite any follow-up plan of correction in an effort to proceed as quickly as possible.

Sincerely,

Vicki Casey
Regional Director for Health Center Operations
Facility Administrator

Enclosures: Photographs of suction machines (Serial Nos. 11310 and 2M1917)
Hand-washing course sign-in sheet
Receipts for heating pads and shelf guard

Planned Parenthood
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Planned Parenthood Great Plains

In-Service Documentation

Location: Columbia
Manager: [redacted]
Date of Training: 9/27/18
Length of Training: 20 min
Title/Topic: Infection Prevention - Hand Washing
Name of Presenter: [redacted]
Presenting Agency: PPGP

STAFF IN ATTENDANCE

Printed Name	Signature
[redacted] NP	[redacted]
[redacted]	
Note: Both nurse practitioners, a licensed practical nurse, the health center manager, and the regional director of health center operations completed the training. A separate sheet reflecting the physician's participation was previously produced to surveyors.	

Managers should complete this form for all required and optional in-service trainings, asking each staff member in attendance to print and sign their names. Attach any additional required pieces of training documentation and submit a copy to the Human Resources Department.

Americans United for Life

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

CHPPGP Second Plan of Correction
Exhibit A - Page 007

Americans United for Life

CHPPGP aspiration machine
Serial No. 11310

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

Americans United for Life

CHPPGP suction machine
Serial No. 2M1917

[redacted]
[redacted]

Subject: Heating Pads
Date: Friday, September 28, 2018 1:34:15 PM

NS
Home Supply

Home Retail Products Who

Thank you. Your order has been received.

ORDER NUMBER:	DATE:	EMAIL:	TOTAL:	PAYMENT METHOD:
6618	September 28, 2018	[redacted]	$190.00	Credit Card

ORDER DETAILS

PRODUCT	
Analog Medical Grade Heating Pad - Medium (18 In. x 14 In.) × 4	
SUBTOTAL:	
SHIPPING:	
PAYMENT METHOD:	
TOTAL:	

BILLING ADDRESS

[redacted]
4401 W 109th St Suite200
Overland Park KS, KS 66211

5732686507

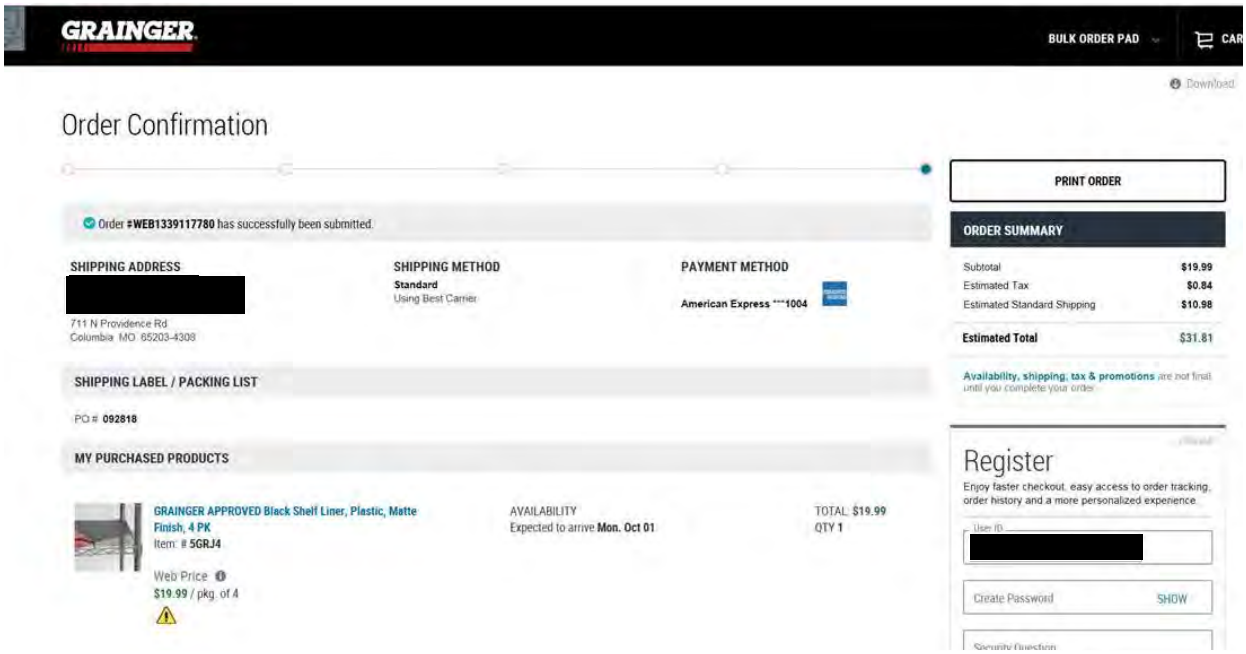
SHIPPING ADDRESS

[redacted]
711 N Providence Rd
Columbia, MO 65203

Americans United for Life

[redacted]

[redacted]
Sent: Friday, September 28, 2018 1:20 PM
[redacted]
Subject: Shelf Guard



[redacted]
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
[redacted]

Americans United for Life

For Plan of Correction Monitoring – CHPPGP Columbia Facility

DATE OF SERVICE: _____

COMPLETED AFTER PATIENT: 1___ 2___ 3___ 4___ 5___ 6___ 7___ 8___ 9___ 10___

COMPLETED BY: _____

Post-Procedure Room Cleaning Checklist

This list is to be used as a guide/quick reference and is not a substitute for the information found in the Infection Prevention Manual. Please see the Infection Prevention Manual for detailed information about specific disinfecting and sterilizing procedures. Follow all directions on each individual cleaning product used.

After Every Procedure:

- ☐ Remove used instruments and place in the dirty room to be cleaned, disinfected and sterilized as required.
- ☐ Replace paper on exam table after wiping exam table with disinfectant wipes and allowing to dry.
- ☐ Replace covers on leg/foot holders.
- ☐ Wipe down all procedure lights including the swing arm light handle and the gooseneck light. Disinfect any spray bottles/other equipment that is not disposable and was not placed inside a sterile cover.
- ☐ Throw out any medications including multi-use vials that were brought into the procedure room (whether or not the patient used them).
- ☐ Collect and remove waste.
- ☐ Collect and remove soiled linen, if any.
- ☐ Clean and disinfect blood pressure cuffs, monitor leads, etc.
- ☐ Wipe down the exam table and other horizontal surfaces that came into contact with patient (including wheelchair, if used) with germicidal disposable wipes.
- ☐ Clean floor with disinfectant wipe around exam table if there are bodily fluids present.
- ☐ Wipe down Procedure trays/carts with germicidal disposable wipes.

If the ultrasound machine was used:

- ☐ Wipe the abdominal transducer with Sono-Wipes.
- ☐ If trans-vaginal probe was used, probe must be sterilized for 8 minutes using Revital–Ox Resert High Level Disinfectant located in the scrub area in the change room then rinse well under running water.
    - Controls must be done prior to disinfecting.
    - Log book for Revital-Ox is located in the procedure room cabinet.

If suction machine was used:

- ☐ Wipe with germicidal disposable wipes and do visual inspection of machine.
- ☐ Remove canister and wipe inside the canister holders.
- ☐ Canisters must be changed, cleaned, disinfected and dried between patients.
- ☐ Single use tubing must be disposed of as infectious waste after each patient.

Americans United for Life

From: Wales, Emily
To: "Loethen, Nikki"
Subject: Checking in re: Columbia license
Date: Monday, October 01, 2018 4:02:00 PM

Hi, Nikki.

I left a message with Emily in your office, but I thought I'd send you a quick email, as well. As you know, the abortion facility license for our Columbia health center is set to expire tomorrow. I'm sure you're aware that we received a new statement of deficiencies on Friday, and we submitted a second plan of correction Saturday.

Fortunately, all of the issues had already been addressed prior to our receipt of the statement. I would note, just so it's clear, that even the requests that we replace or purchase new equipment have been resolved. The items we're replacing that haven't yet arrived from vendors – tables and heating pads – aren't necessary for patient care, so we've removed them, and the shelf guard for our supply room has been purchased and installed.

I wanted to ensure that DHSS's surveyors knew they were welcome to return for a follow-up inspection at any time. We are, of course, eager to keep this process moving to ensure patients are able to access services, and we have patients scheduled this Wednesday and next Tuesday. I know that this inspection process has come down to the wire before, so I'm hopeful we can work together to resolve things in a timely manner.

As always, don't hesitate to call if you have any questions or would like to discuss our license.

Emily

Emily Wales
General Counsel and Chief Compliance Officer
Planned Parenthood Great Plains (PPGP)
Planned Parenthood Great Plains Votes (PPGPV)
P: 913-345-4613
www.PPGreatPlains.org | www.PPGPVotes.org

**Licensed in Missouri and Kansas*

[redacted]

[redacted]

[redacted]

From: Casey, Vicki
Sent: Wednesday, October 03, 2018 4:59 PM
To: 'Cummins, Todd'; 'william.koebel@health.mo.gov'
Subject: RE: CHPPGP Plan of Correction

Bill and Todd,

I wanted to pass along one more update regarding our plan of correction. The new heating pads and tables have been received at the health center, as you'll see in the attached photographs. (We've left the pads in the boxes in case you have questions.) You'll note, of course, that there are still four chairs in the recovery room, as we have not yet heard a response on the waiver.

Please let me know when we can expect an update on the approval status of our plan of correction and the waiver request.

Have a good evening.

Vicki Casey
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
PH: 913-345-4671
vicki.casey@ppgreatplains.org

Americans United for Life

From: Casey, Vicki
Sent: Tuesday, October 02, 2018 3:00 PM
To: 'Cummins, Todd'; 'william.koebel@health.mo.gov'
Subject: CHPPGP Plan of Correction

Bill and Todd,

I just tried to call both of you but wasn't able to reach you. I wanted to check with you on the status of our Columbia license, as the license expires today. I believe you both know we have patients on the schedule tomorrow, and as I stated in my letter to you Friday, all of the issues you raised last week have been addressed.

Also, I wanted to make sure you had the latest information about the new equipment we've ordered. The shelf guard has been installed, and the new tables and heating pads have been ordered. Both should be arriving soon, but since those items aren't necessary for patient care, we've removed the old tables and pads from patient areas. And, of course, you have the photographs of the repaired machines, as you requested during your visit.

Please don't hesitate to give me a call if you'd like to discuss anything. I look forward to hearing from you soon.

Vicki

Vicki Casey
Regional Director of Health Center Operations
Missouri/Kansas
4401 W 109th St Suite 200
Overland Park KS 66211
PH: 913-345-4671
vicki.casey@ppgreatplains.org

Americans United for Life

Missouri Department of Health and Senior Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 12/06/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
{L 000}	Initial Comments A second onsite revisit was conducted at the facility on December 06, 2018 to evaluate the correction of deficiencies cited on the August 14, 2018 licensure survey. An in-person interview was conducted offsite with the facility's physician to evaluate compliance with applicable requirements. All deficiencies cited during the August 14, 2018 licensure survey were found to be corrected. The facility was found to be in compliance with all legal requirements.	{L 000}		

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Randall W. Williams, MD, FACOG
Director

Michael L. Parson
Governor

December 14, 2018

Vicki Casey
Comprehensive Health Of Planned Parenthood Great Plains, Inc.
711 N Providence Road
Columbia, MO 65203

RE: ***Second Revisit Licensure Survey***

Dear Vicki Casey:

Please see attached results of the recent follow-up survey on ***December 6, 2018***. This relates to the Licensure Survey conducted ***August 14, 2018***. Your facility is now compliant with all deficiencies previously cited.

Abortions shall not be performed at CHPPGP until the facility is licensed and in compliance with all applicable laws, including but not limited to the hospital privileges requirements. *See* §§ 188.027, 188.080 & 197.215 RSMo; 19 CSR 30-30.060(1)(C)(4).

Please retain this material for your own records.

Please contact the Bureau of Ambulatory Care with any questions at 573-751-1588 or BAC@health.mo.gov.

Respectfully,

Melinda Laughlin RN, BSN
Chief
Bureau of Ambulatory Care
Division of Regulation and Licensure
PO Box 570
Jefferson City, MO 65102-0570
Phone 573-751-1588
Fax 573-751-6648

Enclosure