April 20, 2017

Dear [Name],

The Division of Hospitals and Diagnostic and Treatment Centers within the New York State Department of Health (the Department) is responsible for assessing compliance with federal and state regulatory requirements at primary and acute care facilities. The assessment is accomplished through various surveillance activities.

As part of the surveillance process, the Department accepts complaints involving patient care and safety issues filed against acute and primary care facilities, and uses the information to direct surveillance activities.

The Department has conducted a survey of operations at [Facility Name], which involved assessment of the facility’s compliance with defined regulatory requirements. Facility operations were assessed during this survey process. Concerns presented in your complaint were included as part of the medical record review used to assess facility operations. The issues of your complaint assisted in directing review of the systems in place at the facility while assessing the minimum standards of the applicable regulatory requirements.

As a result of this review, no regulatory deficiencies were identified specific to the issues raised in your complaint.

Thank you for bringing your concerns to the attention of the Department and providing information to direct our facility surveillance activity.

Sincerely,
Northeast Division of Survey & Certification
July 6, 2016

CMS Certification Number (CCN): 33C0001060
Case Number: [Redacted]

Administrator
[Redacted]

Dear Administrator:

This letter is to certify that you are a participant in the Medicare program in good standing, your last survey was conducted on May 23, 2014 and your status is in compliance with the Federal Regulations as of the date above.

If you have any questions please contact me at [Redacted], or email me at [Redacted].

Sincerely,

[Redacted]
June 25, 2015

Dear [Name]:

This letter is in response to your recent complaint, regarding the facility noted above. The New York State Department of Health Division of Hospitals and Diagnostic and Treatment Centers has reviewed the information that you provided and has determined that the Department will take no further action at this time.

However, this facility is accredited by the Accreditation Association for Ambulatory Health Care (AAAHC), which is responsible for the facility’s compliance with applicable regulations. Should you wish to file a complaint with the accrediting organization, please refer to the information on the reverse side of this letter. You may also consider bringing your concerns to the patient representative at the facility.

Thank you for bringing your concerns to our attention. We will maintain your correspondence in our complaint tracking system. In order to identify similar patient concerns and trends in our facilities throughout New York State, the information you submitted will be periodically reviewed.

Sincerely,
<table>
<thead>
<tr>
<th>Name of Accrediting Organization</th>
<th>Contact Information</th>
</tr>
</thead>
</table>
| **The Joint Commission (TJC)**                                     | **Address:** One Renaissance Boulevard  
|                                                                     | Oakbrook Terrace, IL 60181  
|                                                                     | **Phone:** (800) 994-6610  
|                                                                     | **Website:** www.jointcommission.org |
| **American Osteopathic Association/Healthcare Facilities Accreditation Program (HFAP)** | **Address:** 142 E. Ontario St.  
|                                                                     | 10th Floor  
|                                                                     | Chicago, IL 60611-2864  
|                                                                     | **Phone:** (800) 621-1773, ext. 8063  
|                                                                     | **Website:** www hfap.org |
| **DNV GL - Healthcare (DNV GL)**                                    | **Address:** 400 Techne Center Drive  
|                                                                     | Suite 100  
|                                                                     | Millford, Ohio 45150-2792  
|                                                                     | **Phone:** (866) 523-6842  
|                                                                     | **Website:** www.dnvglhealthcare.com |
| **Accreditation Association for Ambulatory Health Care (AAAHC)**     | **Address:** 5250 Old Orchard Road  
|                                                                     | Suite 200  
|                                                                     | Skokie, IL 60077  
|                                                                     | **Phone:** (874) 853-6060  
|                                                                     | **Website:** www.aaahc.org |
Dear [Redacted],

Staff from the New York State Department of Health completed an onsite survey at [Redacted] on 06/01/2018. The purpose of this surveillance activity was to assess compliance with Title 10 New York Codes, Rules and Regulations (10NYCRR) governing Diagnostic and Treatment Centers.

Enclosed is the Statement of Deficiencies detailing the survey findings.

An acceptable Plan of Correction is due to this office through the ePOC system within ten (10) calendar days of receipt of electronic notification of the posting of the SOD or no later than 06/24/2018.

An acceptable Plan of Correction must relate to the care of all patients and prevent such occurrences in the future. It must contain the following elements:

1. The plan for correcting each specific deficiency cited;
2. The plan for improving the processes that led to the deficiency cited;
3. The procedure for implementing the acceptable plan of correction for each deficiency cited;
4. The title of the person responsible for implementing the acceptable plan of correction, and
5. The process for how the facility has incorporated the improvement action into its Quality Assessment and Performance Improvement (QAPI) program, including monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected.
As you prepare a specific Plan of Correction on the Statement of Deficiencies through the ePOC system, please ensure the following:

1. Corrective actions and the title of the party responsible for each corrective action are entered in the column labeled “Provider’s Plan of Correction,”
2. Completion date for each action plan is entered in the (X5) column, and
3. The first page of the Plan of Correction is signed by a duly authorized representative of your facility in the (X6) section.

Sincerely,

cc: Board Chairman

(Enclosure)
New York State Department of Health

<table>
<thead>
<tr>
<th>Statement of Deficiencies and Plan of Correction</th>
<th>(X1) Provider/Supplier/Lic. Identification Number</th>
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</thead>
<tbody>
<tr>
<td>Name of Provider or Supplier</td>
<td>STREET ADDRESS, CITY, STATE, ZIP CODE</td>
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<thead>
<tr>
<th>(X4) ID Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID Prefix Tag</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-referenced to the Appropriate Deficiency)</th>
<th>(X5) Complete Date</th>
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<tbody>
<tr>
<td>T 000</td>
<td>INITIAL COMMENTS</td>
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<td>PFI #</td>
<td>OPERATING CERTIFICATE #</td>
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The New York Official Compilation of Codes, Rules and Regulations (10NYCRR) deficiencies below are cited as a result of a survey conducted on 5/30/2018 to 6/01/2018 in accordance with Article 28 of the New York State Public Health Law.

The plan of correction, however, must relate to the care of all patients and prevent such occurrences in the future intended completion dates and the mechanism(s) established to assure ongoing compliance must be included.

This survey also included the T2293: See event # 752-1.5 (c) CENTER SERVICES. Pharmaceutical Provisions.

The operator shall ensure that:
(c) expired or deteriorated medications and biologicals are destroyed in accordance with professional standards of pharmacy practice.

This LICENSURE is not met as evidenced by:

Based on observations and interview, the facility failed to ensure that expired medications were removed and not available for patient's use.

Findings include:

During inspection of the emergency medication box on 5/31/18 at 3:40 PM, it was observed that two (2) Epinephrine Auto Injector(medication

The expired medications were removed from the emergency box. Going forward, the Nurse Practitioner who works at this site will do a weekly check of the emergency box to ensure there are no expired medications.

The pharmacy consultant will be notified of this deficiency, and will continue to check for expired medications on her rounds of the SI Center. Any future findings will be reported back to the quarterly Quality Management and Infection Control Committee.

Person Responsible: Clinical Services.

LABORATORY DIRECTOR’S OR PROVIDER/SUPPLIER REPRESENTATIVE’S SIGNATURE

TITLE

Electronically Signed

06/22/2018

Americans United for Life
T2293  Continued From page 1
used for life threatening allergic reaction)
expired on 4/18/18.

During interview with Staff F, Nurse Practitioner
at the time of observation, she acknowledged
the finding.
New York State Department of Health

<table>
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<tr>
<th>STATMENT OF DEFICIENCIES AND PLAN OF CORRECTION</th>
<th>(X1) PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER</th>
<th>(X2) MULTIPLE CONSTRUCTION</th>
<th>(X3) DATE SURVEY COMPLETED</th>
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<td>A. BUILDING</td>
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NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

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<td>The plan of correction, however, must relate to the care of all patients and prevent such occurrences in the future intended completion dates and the mechanism(s) established to assure ongoing compliance must be included.</td>
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<td>This survey also included the following extension clinic:</td>
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<td>See event # 751.8 (c) ORGANIZATION AND ADMINISTRATION.</td>
<td>T2153</td>
<td>7/02/2018</td>
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

If continuation sheet Page 1 of 19
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## Statement of Deficiencies and Plan of Correction

**New York State Department of Health**

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<tr>
<th>(X1) Provider/Supplier/CLIA Identification Number:</th>
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<th>(X3) Date Survey Completed</th>
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<td>[Redacted]</td>
<td></td>
<td>06/01/2018</td>
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</table>

### Name of Provider or Supplier
[Redacted]

### Street Address, City, State, Zip Code
[Redacted]

### Summary Statement of Deficiencies
(Each deficiency must be preceded by full regulatory or LCS identifying information)

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<th>ID Prefix Tag</th>
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<td>T2153</td>
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### Provider's Plan of Correction
(Each corrective action should be cross-referenced to the appropriate deficiency)

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<tr>
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<td>T2153</td>
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</table>

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*Americans United for Life*
| T2153 | Continued From page 4 | T2153 |
T2153
Continued From page 5

T2170
751.9 Organization and Administration.

Patients’ rights.
Policies and procedures shall be developed and implemented regarding the patients’ rights. The operator shall have in effect a written statement of patients’ rights which is prominently posted in patient care areas and a copy of which is given to the patient.

This LICENSURE is not met as evidenced by:

Based on observation and interview the facility failed to ensure:
1. That a written statement of Patients Rights was posted in an area accessible to patients;
2. The written statement was updated to include all the requirements by the NYS Department of Health;
3. A copy of Patient Rights information is provided to each patient.

Finding include:
1. During tour of the facility waiting area on the on 5/30/18 at approximately 11:30 AM, it was observed that a written statement of Patient Right’s was posted behind the reception desk and was not accessible to patients.

T2153

known by the staff member why they are being observed. The next convening of the quarterly Quality Management and Infection Prevention meeting will be held at the end of September.

I. [redacted], attest that all center staff including Health Care Assistants and Nurses were re-trained on the above practices on June 21, 2018.

T2170

1. Plan of Correction – Patients’ Rights

07/31/2018

1. That a written statement of Patients’ Rights was posted in an area accessible to patients – Patients’ Rights poster has been relocated to a predominant area of the Check IN desk on the where patients can clearly see and access information provided. Additionally, posters will be added to and waiting areas.

2. The written statement was updated to include all the requirements by the NYS Department of Health – Document was updated to include that following passage that was previously missing from posted bill of rights – “Make known your wishes in regard to anatomical gifts. You may document your wishes in your health care proxy or on a donor card, available from the center”.

3. A copy of Patient Rights information is provided to each patient. Patient Bill of Rights will be included in patient information packet given at the desk. Additional copies will be available in the waiting areas.
### New York State Department of Health

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**

**STREET ADDRESS, CITY, STATE, ZIP CODE**

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| T2170 | Continued From page 6 | 2. Review of the written statement revealed that a required element (#17) of the New York State (NYS) Patient's Bill of Rights for Diagnostic and Treatment Center & Clinics was missing. The NYS requirement notes, "Make known your wishes in regard to anatomical gift. "You may document your wishes in your health care proxy or on a donor card available from the center."

3. Interview conducted with Patient #1 on 06/18, she stated she did not receive a copy of the Patients Bill of Right's.

At interviews with two more patients, Patient #s 2 and 3 on 06/18 between and , they stated that a copy of Patient Bill of Rights not given to them.

During interview on 06/31/18 Staff B, Assistant Vice President Clinical Services, she confirmed findings and stated that a copy of Patient's Rights is only provide to patients upon their request.

| T2291 | 752-1.5 (a) (2) (iii) CENTER SERVICES. Pharmaceutical Provisions. | The operator shall ensure that:
(a) when there is a pharmacy onsite, it is registered with the State Education Department and meets applicable sections of Part 80 of this Title:

(b) there is a pharmaceutical services committee which shall include, but need not be limited to, the medical director, administrator, pharmacist and, when nursing services are provided, a registered professional nurse. The committee shall:

(iii) be responsible for the development, implementation and review of policies and procedures for obtaining, dispensing, controlling, |

| T2291 | Review of the facility infection prevention manual titled "Safe Injection, Infusion and Medication Vial Practices", last revised 2015 noted the following: If the medication is prepared in bulk for the day's cases, or if the clinical staff preparing the medication participates in another function prior to administration, the syringe or the containers must be labeled. Medication solution labels will include the following: Medication name, Strength, Quality, Diluent and Volume, and expiration time when expiration occurs less than 24 hours.

Staff will verify all medications or solution labels both verbally and visually. Verification is done by two individuals.
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING

(X3) DATE SURVEY COMPLETED

06/01/2018

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

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<tr>
<td>T2291</td>
<td>Continued From page 7 storing, administering and utilizing medications and biologicals in the center, and other related pharmaceutical matters. This LICENSURE is not met as evidenced by: Based on observation, document review, and interview, the facility failed to implement its policy and procedure to ensure that medications prepared in bulk for subsequent use during the day are appropriately labeled. This failure has a potential to cause errors in drug administration. Findings include: Review of the facility infection prevention manual titled &quot;Safe Injection, Infusion and Medication Vial Practices&quot;, last revised 2015 noted the following: If the medication is prepared in bulk for the day's cases, or if the clinical staff preparing the medication participates in another function prior to administration, the syringe or the containers must be labeled. Medication solution labels will include the following: Medication name, Strength, Quality, Diluent and Volume, and expiration time when expiration occurs less than 24 hours. Staff will verify all medications or solutions labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it&quot;. - Staff have been informed of the need to label any medication that is being prepared and not immediately administered by the licensed person who prepared it. Pre-printed labels had already been purchased, and are now in use. Labels include: medication name, strength, quality, diluent and volume, and expiration time when expiration occurs within less than 24 hours. Going forward, staff will verify all medication or solutions labels both verbally and visually. Title of Person Responsible for implementing the acceptable plan of correction: [redacted] [redacted] There will be a question added to the infection control observation tool regarding proper labeling of medications. Any corrective actions will be reported to the quarterly Quality Management and Infection Control Committee meetings.</td>
<td>T2291 qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it&quot;. - Staff have been informed of the need to label any medication that is being prepared and not immediately administered by the licensed person who prepared it. Pre-printed labels had already been purchased, and are now in use. Labels include: medication name, strength, quality, diluent and volume, and expiration time when expiration occurs within less than 24 hours. Going forward, staff will verify all medication or solutions labels both verbally and visually. Title of Person Responsible for implementing the acceptable plan of correction: [redacted] There will be a question added to the infection control observation tool regarding proper labeling of medications. Any corrective actions will be reported to the quarterly Quality Management and Infection Control Committee meetings.</td>
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<tr>
<td>T2291</td>
<td>Continued From page 8 expiration time.</td>
<td>T2291</td>
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<td>During interview with Staff L, [redacted] during the time of observation, he stated that the Propofol expires in 6 hours after preparation and that he drew the Propofol syringes at 9:00 AM.</td>
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<td>2. Four (4) 10 cubic centimeters (cc) syringes of Lidocaine 1% and two (2) 3cc syringes of Lidocaine 1% were not labeled with expiration time.</td>
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<td>During interview with Staff N, [redacted] she reported that she prepared the Lidocaine syringes for the physician's use.</td>
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<td>There was no indication that the six (6) syringes of Lidocaine were verified by another qualified professional participating in the procedure as prescribed by the policy.</td>
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<td>702.1 (c) (1) ENGINEERING AND MAINTENANCE.</td>
<td>U7011</td>
<td>1) Upon testing the air flow of the sterilization and decontamination rooms it was noted to be neutral. Negative air pressure is maintained in the decontamination room when the door is closed and the pass through is closed. Positive air pressure is maintained in the sterilization room when the door is closed and the pass through is closed. Staff have been instructed to keep the doors to both rooms closed when in use and to keep the pass through doors closed when not in use. And, for the pass through only one door should be opened at a time.</td>
<td>07/13/2018</td>
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<td>Ventilation, heating, air conditioning, and air changing systems shall:</td>
<td>U7011</td>
<td>2) The facility also did not monitor the temperature and humidity in these rooms. Thermostats will be installed in the decontamination and sterilization room by July 13, 2018. Daily logs will be kept.</td>
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<td>(1) be maintained in good repair and shall be operated in a manner which will prevent the spread of infection and provide for patient or resident health and comfort.</td>
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<td>This LICENSURE is not met as evidenced by:</td>
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<td>Based on observation and staff interview, the facility failed to maintain the ventilation, heating, air conditioning and air circulation in a manner to prevent the spread of infection.</td>
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<td>Findings include:</td>
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<td>During the tour of the facility on 05/30/2018 at approximately 11:30 AM, it was noted that the</td>
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<tr>
<td>U7011</td>
<td>Continued From page 9 doors of the Decontamination room and the Sterilization room were both kept wide open. In addition, the pass through window between the Decontamination room and the Sterilization room was also observed to be kept wide open at all times. Upon interview of staff H on 05/30/2018 at approximately 11:45 AM, it was revealed that the staff kept the doors of the Sterilization room and the Decontamination room open as it was hot and humid in the rooms. Upon testing the air flow of the two rooms, it was noted to be neutral. Instead, the Sterilization room must have positive airflow in relation to the corridor and the Decontamination room must have negative air flow, in relation to the corridor. The facility also did not monitor the temperature and humidity in these rooms.</td>
<td>U7011</td>
<td>both rooms to monitor the temperature and humidity. Staff assigned to work in the room will be responsible for logging the temperature and humidity of the room. Infection control manual will be updated by July 1, 2018 to include information on maintaining negative air pressure in the decontamination room and positive air pressure in the sterilization room. Infection Control observation checklist will also be updated by July 1, 2018 to include maintenance of negative air pressure in the decontamination room, positive air pressure in the sterilization room and monitoring of temperature and humidity in both rooms. Responsible party: [Redacted] The updated infection control observations will be completed for use during the 3rd quarter observations. Going forward, staff will be required to present the findings of their infection control and environmental rounds observations, including any corrective actions that were made, at the quarterly Quality Management and Infection Prevention meeting. Staff observations will happen within the context of other observations, and it will not necessarily be known by the staff member why they are being observed. The next convening of the quarterly Quality Management and Infection Prevention meeting will be held at the end of September.</td>
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
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<tbody>
<tr>
<td>U7026</td>
<td></td>
<td><strong>Continued From page 10</strong> 702.2 (a) HOUSEKEEPING.</td>
<td>U7026</td>
<td></td>
<td><strong>Sterilization Room:</strong></td>
<td>07/24/2018</td>
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<tr>
<td>U7026</td>
<td></td>
<td>The entire facility, including but not limited to the floors, walls, windows, doors, ceilings, fixtures, equipment, and furnishings, shall be maintained in good repair, clean and free of insects, rodents and trash.</td>
<td></td>
<td></td>
<td>1) The floor of the sterilization room was heavily soiled and grimy. A deep cleaning to remove the grime will occur on June 25, 2018. Floors are mopped daily in the evening by housekeeping. A facility coordinator will check the room daily in the morning to ensure cleanliness and note in a log the status of the room.</td>
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<td><strong>This LICENSURE is not met as evidenced by:</strong></td>
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<td>2) A wall-mounted fan was observed to be in the sterilization room and it was noted to be laden with dust. Staff were observed wrapping up instruments for sterilization under the dust fan that was blowing air. The fan will be removed from the room, and an air conditioner installed to maintain the temperature between 72-78 degree Fahrenheit.</td>
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<td><strong>Findings include:</strong></td>
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<td>3) The ceiling tiles in the sterilization room were discolored with black dust mites hanging on them. The ceiling tiles had pores on them and were not cleanable and washable type. New washable ceiling tiles have been ordered and will be installed by July 20, 2018. They will be cleaned monthly by housekeeping. A facility coordinator will check the room daily in the morning to ensure cleanliness and note in a log the status of the room.</td>
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<td>During the tour of the Sterilization Room on 05/30/2018 at approximately 11:30 AM, the following were observed:</td>
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<td>4) Clean items were not stored in an organized manner. Plastic containers containing spare instrument and other supplies were stored together. All of these items have been removed from the room. Added to the infection control observation tool will be a question to ensure that the</td>
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<td>1. The floor of the Sterilization room was heavily soiled and grimy. A deep cleaning to remove the grime will occur on June 25, 2018. Floors are mopped daily in the evening by housekeeping. A facility coordinator will check the room daily in the morning to ensure cleanliness and note in a log the status of the room.</td>
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<td>2. A wall mounted fan was observed to be functioning in the sterilization room and it was noted to be laden with dust. Staff were observed wrapping up instruments for sterilization under the dusty fan that was blowing air.</td>
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<td>The clean items were not stored in an organized manner. Plastic Containers containing spare instruments and other supplies were stored together.</td>
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<td>During the tour of the Sterilization room, it was noted that the clean supplies were stored in plastic containers under the handwashing sink.</td>
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<td></td>
<td>During the tour of the Decontamination room on</td>
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Continued From page 11

05/30/2018 at approximately 12:30 PM, it was noted that there was no separation between clean and dirty areas. The decontamination room did not have a handwashing sink and therefore the staff performed handwashing in the clean sterilization room.

The 3 sinks used for tissue examination and decontamination of metal trays did not have wrist blades and therefore the staff were observed operating the sinks with soiled hands.

Storage of clean supplies including 4 cans of sterile water, unopened bottles of sporax solutions, detergents etc were observed under the decontamination sinks.

The floor of the decontamination room was also heavily soiled. The vent in the room was laden with dust and the ceiling tiles were observed to be black in color.

only items in the room are items used to sterilized instruments.

5) Clean supplies were stored in plastic containers under the handwashing sink. All items have been removed from under the handwashing sink.

Decontamination Room:

1) The decontamination room didn't not have a handwashing sink and therefore the staff performed handwashing in the clean sterilization room. A soap dispenser has been added to the decontamination room and staff can now wash their hands in the sink.

2) The 3 sinks used for tissue examination and decontamination of metal trays did not have wrist blades and therefore the staff were observed operating the sinks with soiled hands. Wrist blades will be installed on all of the sinks in the decontamination room by July 6, 2018.

3) Storage of clean supplies including 4 cans of sterile water, unopened bottles of sporax solution, detergents etc. were observed under the contamination sinks- All items have been removed from underneath the sink.

The floor of the decontamination room was also heavily soiled the vent in the room was laden with dust and the ceiling tiles were observed to be black in color. A deep cleaning to remove the grime will occur on June 25, 2018. Floors are moppe in the evening by housekeeping. The vent in the room was cleaned on 5/30/18.
vent will be cleaned weekly going forward. A facility coordinator will check the room daily in the morning to ensure cleanliness and note in a log the status of the room.

Responsible Party: [Redacted]

Environmental rounds observation checklist will also be updated by July 2, 2018 to include that no supplies are to be stored under the sinks in the decontamination or sterilization rooms. Housekeeping cleaning schedules will be updated by 6.30.18 to ensure that ceiling tiles are cleaned monthly and vents weekly. Going forward, staff will be required to present the findings of their infection control and environmental rounds observations, including any corrective actions that were made, at the quarterly Quality Management and Infection Prevention meeting. The next convening of the quarterly Quality Management and Infection Prevention meeting will be held at the end of September.

1. Based on review of documents, the facility did not have policies to guide the staff regarding the process of sterilization and high-level disinfection.

   a. The policies did not indicate the chemical disinfectant used in the process of high-level disinfectant and the required time of exposure for the various instruments used in the sterilization/high-level disinfection.

The Infection Control manual will be...

<table>
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<tr>
<th>U7026</th>
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<tr>
<th>U7046</th>
<th>702.4 (a) INFECTION CONTROL AND REPORTING.</th>
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</table>

Medical facilities shall:

(a) Establish an infection control committee, composed of representative staff, which shall be responsible for establishing policies and procedures for investigating, controlling and preventing infections in the facility. The policies and procedures shall include those for the isolation of patients with communicable or infectious diseases or patients suspected of having such diseases, for training all personnel...
Continued From page 13
rendering care to such patients in the employment of standard infection control techniques, and for obtaining periodic reports of nosocomial infections. Nosocomial infections shall include an increased incidence or outbreak of disease due to biological, chemical or radioactive agents or their toxic products occurring in patients or persons working in the hospital. The committee shall establish methods to ensure that policies and procedures are executed and the infection control program is effective.

This LICENSURE is not met as evidenced by:

Based on observation, review of documents and staff interview, the facility failed to ensure that:

1. the sterilization of surgical equipment was performed and recorded by staff in accordance with CDC recommendation and AAMI standards.
2. staff verified that the load of instrument trays underwent proper sterilization prior to being released to the procedure rooms.
3. staff use appropriate Personal Protective Equipment (PPE) while performing clean and dirty tasks.

Findings include:

1. Based on review of documents, the facility did not have policies to guide the staff regarding the process of sterilization and high-level disinfection.

a. The policies did not indicate the chemical disinfectant used in the process of high-level disinfectant and the required time of exposure for the various instruments used in the sterilization/high-level disinfection.

b. The policies did not instruct the staff on manual cleaning of instruments in accordance with CDC recommendations, prior to be machine washed and sterilized.

The Infection Control manual will be updated to include specific step-by-step instructions on manual cleaning of instruments in accordance with CDC recommendations, prior to being machine washed and sterilized.

c. The facility did not have policies to guide the staff on the sterilization process for colposcopy trays.

The Infection Control manual will be updated to include specific step-by-step instructions on the proper technique for high-level disinfection vs. sterilization. Staff will be re-trained to understand the difference.

d. The policies did not guide the staff on the process to verify that the load of instruments had been properly sterilized, in order to be released to the procedure rooms.

Facility will begin recording and maintaining a sterilization log that includes the following:

- Lot or load number
Continued From page 14

b. The policies did not instruct the staff on manual cleaning of instruments in accordance with CDC recommendations, prior to be machine washed and sterilized.

During observation of the decontamination process performed by a [redacted] (Staff Q) on the soiled surgical instruments on 05/30/2018 at approximately 12:30 PM, it was observed that the instruments were wiped down using a dry wipe, placed into metal baskets and then loaded into the washer. The staff member did not pre-clean the speculums and the other instruments on the tray to remove the gross contamination, prior to being loaded into the washer.

c. The facility did not have policies to guide the staff on the sterilization process for colposcopy trays.

During the inspection of the decontamination room, a plastic container with Sporax II solution was observed on a plastic cart. Upon interview of Staff Q at approximately 12:45 PM, it was stated that the colposcopy instruments were disinfected by soaking in Sporax II solution for 30 minutes. The staff member was not able to verbalize the level of disinfection/sterilization achieved by soaking these instruments in Sporax II. The manufacturer’s Direction For Use and Standard of Practice for Infection Prevention recommends 6 hour soak in hydrogen peroxide 7.5% (Sporax II) for Sterilization of Critical items.

d. The policies did not guide the staff on the process to verify that the load of instruments had been properly sterilized in order to be released to the procedure rooms.

- Specific contents of the load, quantity and name of instruments
- Exposure time and temperature
- Name / initials of operator
- Response of the CI (chemical Indicator) from load

All instruments / trays in load will be marked with:
- date of sterilization
- load number from which it was sterilized
- initials of operator

e. The policies did not instruct the staff to perform Biological Indicator (BI) tests daily in accordance with CDC recommendations.

Facility will begin biological indicator testing on a daily basis per CDC guidelines as well as maintaining sterilization logs.

Biological Indicator Testing
- The results of the biological test will be documented in a log book and maintained for three years.
- Documentation will include the date of the test, staff member who performed the test and results of the test.
- Daily BI tests will be run and results documented before releasing contents of the autoclave to the procedure rooms.

The Infection Control observation checklist will be updated to include more specific information about biological indicator testing and sterilization logs to ensure the ongoing adherence to the above mentioned guidelines.
### Summary Statement of Deficiencies

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<tr>
<td>U7046</td>
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#### E. The policies did not instruct the staff to perform Biological Indicator (BI) tests daily in accordance with CDC recommendations.

During review of the Biological Indicator (BI) test results on 05/30/2018 at approximately 2:00 PM, it was noted that the facility conducted the Biological Indicator tests only once a week. Upon interview of Staff H at approximately 12:00 noon, it was stated that sterilization staff sent out the spore vials to the laboratory once a week but were not made aware of the results. Therefore, the sterilization staff released the load without being aware of the BI test results. CDC recommends that BI tests be conducted on a daily basis and on the load that has implants. Therefore the facility's practice of conducting BI tests once per week was found to be not in accordance with CDC recommendations.

#### 2. During review of the steam sterilization process with Staff H on 05/30/2018 at approximately 12:00 noon, it was noted that the staff member did not place Chemical Indicator (CI) strip inside the sterilizer along with the load of wrapped trays. Upon interview, the staff member stated that the trays were considered to be sterilized when the stripes on the wrapping tape turned black after the cycle was done. The staff member does not confirm that the sterilizer reached the required temperature of 270 degrees Fahrenheit and did not confirm that the cooking time was 3-4 minutes.

The facility's policy "Guidelines For Use Of Sterilization Indicator Tape" stated that "Dark Stripes on package tape do not absolutely prove that instruments are sterile." However, the policy

2. See above for implementation of sterilization log. Specific instructions for ensuring proper sterilization will accompany the log.

3. There has been an initial re-training on proper usage of PPE for all staff who work with patients. Infection Control observations will happen with the updated tool to include all staff within the next month. Results of these observations will be reported to the Infection Control Committee and at the next quarterly Quality Management and Infection Control Committee meeting.

Title of Person Responsible for Implementing the Acceptable Plan of Correction: [Redacted]
New York State Department of Health

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<tr>
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<tr>
<td>U7046</td>
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<td>Continued From page 16 failed to guide the staff on the process required to ensure sterility of instruments after steam sterilization.</td>
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<td>Therefore the staff practice of releasing the load of instrument trays to the procedure rooms were in direct contrast to CDC recommendations and facility policy.</td>
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<td>3. During tour and observation on May 30, 2018 at 11:55AM Staff K a [redacted] was observed cleaning soiled surgical equipment without wearing goggles and a gown.</td>
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<td>Staff K was also observed going from a dirty task to a clean task without changing gloves in between. Specific reference is made to Staff K who was observed handling Products of Conception (POC) and wiping the soiled and bloody surgical equipment then after removing the equipment from the disinfectant proceeded to place the disinfected surgical equipment on the clean counter to dry. All of these procedures were done with the same pair of gloves.</td>
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<td>Staff H ([redacted] trainer) was observed: -- going from the dirty room to the autoclave room wearing the same gloves. Furthermore, she entered information into the computer wearing the same gloves that she used to handle the soiled surgical equipment.</td>
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<td>During tour and observation on May 31, 2018 at 11:10AM Staff H was observed packing surgical instrument into a metal tray in the Autoclave room with out using gloves.</td>
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<td>On May 31, 2018 at 11:40 AM Staff I (HCA) was observed wearing her PPE gown with the sleeves tied around her back and not covering</td>
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<td>U7046</td>
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<td>Continued From page 17 her arms.</td>
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<td>Staff have been reminded of the importance of keeping clean and dirty linens separate through distribution of a memo, and by reviewing the memo in person in huddles. The dirty linen hamper has been moved to a location within the recovery room so that items may be placed there immediately after use. In addition, staff were reminded not to store any linens on the floor. A question is being added to the environmental rounds observation tool to check for the proper storage of linens. The findings of these observations will be reported out at the quarterly Quality Management and Infection Control Committee. Title of Person Responsible for implementing the acceptable plan of correction:</td>
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Moreover, Staff I instead of changing her gloves and performing hand hygiene and donning a new pair of gloves after cleaning the organic material off the surgical instruments, she proceeded to wash her hands with the gloves on.

Facility policy and procedure written 2015, chapter 2 Direction for Cleaning and Disinfection states, use the appropriate PPE prior to cleaning medical instruments. (i.e. water resistant gown, mask, puncture resistant gloves and eye protection)

On 6/1/2018 at approximately 2:30PM, Staff C. (Center Director) stated that "we will revisit this". 702.5 (d) LINEN AND LAUNDRY.

The governing authority or operator shall: (d) Handle, store and process laundry in a manner that will prevent the spread of infection and assure the maintenance of clean linen.

This LICENSURE is not met as evidenced by:

Based on observations and interview, the facility failed to ensure that linen is stored to prevent contamination and there is a separation of clean and dirty supplies of linen.

Findings include:

During a tour of the on 5/31/18 at 12:30 PM, three linen bags were observed on the floor next to a hamper containing dirty linen.

During interview with Staff E, at the time of observation, she confirmed that the three bags on the floor contained clean
New York State Department of Health

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<tr>
<td>U7059</td>
<td>Continued From page 18 supplies of linen.</td>
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A Title 18 Allegation Survey was conducted on 7/12, 7/13 & 7/14/16 in order to determine compliance in accordance with regulations 42 CFR 416 (Conditions for Coverage) Subpart B and at 42 CFR Part 488 Subpart A for Ambulatory Surgery Centers (ASC).

The Condition for Coverage for Surgical Services was assigned for investigation.

No deficiencies were identified for this investigation.
December 29, 2014

Re:  Article 28 Diagnostic & Treatment Center Survey of December 18 – 22, 2014

Dear [Redacted]

This is to advise you that no deficiencies were identified at the time of the above-referenced survey.

If you should have any questions, please feel free to contact IPRO's Administrative Coordinator, [Redacted]

Sincerely,

[Redacted]

CC: [Redacted]
January 15, 2015

Re: Article 28 Diagnostic & Treatment Center Survey of December 18 - 22, 2014
PFI# [Redacted]

Dear [Redacted]:

Enclosed is the signed copy of the Statement of Deficiencies and Plan of Correction Form.
Please contact me at [Redacted] or at [Redacted] if you have any questions.

Sincerely,
Operating Certificate: 
A Re-licensure survey was conducted at the following date: 12/18-19/2014;

NOTE: THERE WERE NO DEFICIENCIES IDENTIFIED FOR THIS ARTICLE 28 SURVEY OF THE ABOVE NOTED.
ACTS Complaint/Incident Investigation Report

PROVIDER INFORMATION

Name: [Redacted]
Address: [Redacted]
City/State/Zip/County: [Redacted]
Telephone: [Redacted]
License #: [Redacted]
Type: [Redacted]
Medicaid #: [Redacted]
Administrator: [Redacted]

INTAKE INFORMATION

Taken by: [Redacted]
Location Received: [Redacted]
Intake Type: Complaint
Intake Subtype: State-only, licensure
External Control #: [Redacted]
SA Contact: [Redacted]
RO Contact: [Redacted]
Responsible Team: [Redacted]
Source: [Redacted]

Received Start: 2/14/2014 At 09:52
Received End: 2/14/2014 At 09:52
Received by: Hotline
State Complaint ID: [Redacted]
CIS Number: [Redacted]

COMPLAINANTS

Name: [Redacted]
Address: [Redacted]
Phone: [Redacted]
EMail: [Redacted]

Link to: [Redacted]
Relationship: self
Confidentiality Requested: Y

RESIDENTS/PATIENTS/CLIENTS

Name: [Redacted]
Admitted: [Redacted]
Location: [Redacted]
Room: [Redacted]
Discharged: [Redacted]
Link ID: [Redacted]

ALLEGED PERPETRATORS - No Data

INTAKE DETAIL

Date of Alleged: [Redacted]
Time: [Redacted]
Shift: [Redacted]
Standard Notes: Triaged as state MODERATE

DOB: [Redacted]

[Redacted] states she went to the [Redacted] on [Redacted] to have an abortion. She alleges on [Redacted] she was admitted to [Redacted] for an [Redacted] and [Redacted] She alleges she [Redacted] the [Redacted] from the abortion.

4/14/14 Reassigned
5/20/14 Reassigned

Extended RO Notes: [Redacted]
Extended CO Notes: [Redacted]

ALLEGATIONS

Category: Infection Control
Subcategory: Infection Control Practices
Seriousness: Moderate
Findings: Unsubstantiated Lack of sufficient evidence
Details:

Findings Text:
ACTS Complaint/Incident Investigation Report

SURVEY INFORMATION

Event ID   Start Date   Exit Date   Team Members   Staff ID
3Q1S11     05/23/14    05/23/14

Intakes Investigated: [Redacted] (Received: 01/14/2014)

SUMMARY OF CITATIONS:

Event ID   Exit Date   Tag
3Q1S11     05/23/14

State - Not Related to any Intakes
T2069-ORGANIZATION AND ADMINISTRATION.
T0000-INITIAL COMMENTS

EMTALA INFORMATION - No Data

ACTIVITIES

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<th>Completed</th>
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<td>04/23/2014</td>
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<td>07/08/2014</td>
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<td>07/08/2014</td>
<td></td>
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<tr>
<td>Schedule Onsite Visit</td>
<td>05/23/2014</td>
<td>05/23/2014</td>
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ACTS Complaint/Incident Investigation Report

LINKED COMPLAINTS - No Data

DEATH ASSOCIATED WITH THE USE OF RESTRAINTS/SECLUSION - No Data

Reason for Restraint:
Cause of Death:

NOTICES

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PROPOSED ACTIONS

Proposed Action
State Only Actions
None

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Closed: 07/03/2014
Reason: Paperwork Complete

END OF COMPLAINT INVESTIGATION INFORMATION
July 3, 2014

Re: Complaint #

Dear [Name],

This letter follows the completion of a complaint investigation. The allegation was related to a procedure performed at the [Facility Name] and concerns related to infection control.

An unannounced onsite visit was made to the facility on 5/23/14. The investigation included a review of the patient’s medical records, the facility’s internal investigation, and facility policies and procedures. Information provided by the complainant was also considered.

Based on our review, a concern was identified related to the storage of clean supplies. The outcome of our investigation is reflected in the attached Statement of Deficiencies. However, since appropriate corrective measures have already been implemented, no further Plan of Correction is required.

This deficiency citation relates to non-compliance with the provisions of Title 10, NYCRR (Health) and does not preclude any additional administrative action by this Department.

Section 18 of the Public Health Law requires the Department of Health to provide Board members or trustees of voluntary facilities with notices of violations of Public Health Law or other regulations. A copy of the form transmitting the summary notice is attached. If you have any questions concerning this letter, please feel free to me at [Contact Information].

Sincerely,

[Signature]

[Attorney's Name]

[Facility Name]

CC: [Contact Information]
NEW YORK STATE DEPARTMENT OF HEALTH

STATEMENT OF DEFICIENCIES ABSTRACT

FACILITY: 

TYPE OF SURVEY: Complaint Investigation

DATE OF SURVEY: July 3, 2014

On the date specified, staff of this office completed a survey of this health care facility for the purpose(s) indicated. Deficiencies were noted in the areas of operation identified below and/or on the reverse.

751.5 Organization and Administration

This Notice of Violation is provided to you in accordance with Section 18 of the New York State Public Health Law. Section 18 requires the Department of Health to send to each director or trustee of a facility notice of a violation of the Public Health Law or the Department’s regulations, which could result in the revocation, cancellation, limitation, or suspension of the facility’s operating certificate.

The full Statement of Deficiencies was sent to the facility Administrator and the Chairperson or other designated principal contact of the governing body, with the expectation that its contents would be made available to you. Please take time to secure it and review it. Each deficiency cited is a violation of State and/or Federal regulations and may result in the imposition of a fine and/or other penalty against the facility and/or the revocation, cancellation, limitation, or suspension of its operating certificate. As a member of the facility’s governing body, you are responsible for completely correcting the identified deficiencies in a timely manner.

Hospital Program Director

cc: all board members
### T000 INITIAL COMMENTS

**PFI #** [redacted]

**OPERATING CERTIFICATE #** [redacted]

**NOTE:** THE NEW YORK OFFICIAL COMPILED CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF COMPLAINT # [redacted] THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

NO PLAN OF CORRECTION IS REQUIRED FOR THIS STATEMENT OF DEFICIENCIES AS THE FACILITY HAS INITIATED CORRECTIVE ACTION.

### T000 751.5 (a) (13) ORGANIZATION AND ADMINISTRATION.

Operating Policies and Procedures

The operator shall ensure:

(a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice which include but are not limited to:

(13) the operation, maintenance and security of the center.

This Regulation is not met as evidenced by Based on observation and interview the provider failed to implement policies and procedures regarding the storage of clean supplies.

**Findings:**

[Signature and Title]
On 5/23/14 a tour of the provider's clinic was conducted with the Chief Operating Officer and a nurse. At 15:20 clean supplies were noted in the dirty room. The \textit{Infection Prevention Program} was reviewed. The \textit{Infection Prevention Program} addresses all areas of operations and the prevention of infection. The section pertaining to the cleaning and storage of supplies does not make specific reference to the location where clean supplies should be stored.

On 6/17/14 at 4:40 pm the provider's Director of \textit{\textbf{P}} was interviewed regarding provider policies procedures. The discussion focused on the \textit{\textbf{P}}, and specifically the storage of clean supplies.
July 3, 2014

Re: [Redacted]
Complaint # [Redacted]

Dear [Redacted],

This letter is to inform you of the results of the investigation of your complaint against the above referenced facility. The allegations related to care you received at the [Redacted]

This investigation included an onsite visit, interview of staff, a review of your medical record and a review of policies and procedures. The concerns identified in your complaint to the Department were reviewed. A concern was identified related to the storage of supplies. The Department will be working with the provider to ensure corrective measures are implemented.

Thank you for bringing your concerns to our attention.

Sincerely,

[Redacted]
INTAKE INFORMATION

PROVIDER INFORMATION:
Name:
Address:
City/State/Zip/County:
Telephone:
License #:
Type:
Medicaid #:
Administrator:

INTAKE INFORMATION:
Intake Number:
Taken by - Staff:
Location Received:
Intake Type: Complaint
Intake Subtype: State-only licensure
SA Contact:
RO Contact:
Responsible Team:
Source:

Received Start: 04/14/2014 At 09:52
Received End: 04/14/2014 At 09:52
Received by: Hotline

State Complaint ID:
CIS Number:
External Control #:

COMPLAINANTS:
Name:
Address:
Phone:
Email:
Link ID:
Relationship: self
Confidentiality Requested: Y

RESIDENTS/PATIENTS/CLIENTS:
Name:
Admitted: 2013
Location:
Discharged: 2013
Room:
Link ID:

INTAKE DETAIL:
Date of Alleged Event:
Time:
Shift:

Standard Notes: Triaged as state MODERATE

DOB: 

states she went to the on 4/14 to have an abortion. She alleges 

4/14/14 Reassigned to 

5/20/14 Reassigned to

Extended RO Notes:
Extended CO Notes:

ALLEGATIONS:
Category: Infection Control
Sub-category: Infection Control Practices
Seriousness: Moderate
Details:

Reason for Restraint:
Cause of Death

END OF INTAKE INFORMATION
Dear [Name],

Pursuant to Article 28 of the Public Health Law and Section 400.3 of 10NYCRR, I hereby request a copy of the Admission History & Physical, physician and nurses notes surrounding [Patient's Name]’s 13 visit. In addition, please submit a copy of the facility’s internal investigation into the matter.

Should you have any questions in regard to this request, I may be contacted at [Contact Information].

Thank you for your cooperation.

Sincerely,

[Name]

New York State Department of Health
HI, addresses

I have updated this to reflect the issues. This will be sent to all staff today. Please call if you have questions or other recommendations.

Thank you

Warning: This message is intended only for the person listed above. The attached information is protected health information and considered privileged by law. If the reader of this fax is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this information is strictly prohibited. If you are not the recipient, please notify us and shred this information. Thank you for your cooperation.
CERTIFICATION

Pursuant to Section 4518 of the Civil Practice Law and Rules. This is to certify that, to the best of my knowledge, the attached is an exact copy of the original medical record which I have in my custody and control which may be released under the Public Health Law.

There are 38 pages contained in this certified copy, including the certification page.

The medical records were made and kept in the regular course of the business of the agency and is the regular course of the business of the agency to make such medical records (at or about the time of the events described in the medical records).

[Handwritten date and signature]
April 17, 2014

Dear [Redacted],

Pursuant to Article 28 of the Public Health Law and Section 400.3 of 10NYCRR, I hereby request the medical records for [Redacted] for her [Redacted] and [Redacted] department visits as well as the History & Physical for her [Redacted] admission. This request is not as a result of a complaint against [Redacted].

This submission should include physician and nursing progress notes, laboratory tests, physician orders, medication sheets and all other documents in the patient files. Any written explanation of the record may accompany the file but cannot be accepted in lieu of it.

Please return these records as soon as possible, to my attention. Should you have any questions in regard to this request, I may be contacted at [Redacted].

Thank you for your cooperation.

Sincerely,

[Redacted]

Consultant Nurse
July 29, 2014

Re: Article 28 Survey

Dear [Name]

The Plan of Correction for the Statement of Deficiencies dated April 24, 2014, which you submitted, has been reviewed by this office and is acceptable.

Please continue to implement this Plan of Correction. This office reserves the right to re-survey for compliance with these code sections at any time.

Should you have any questions you may contact this office at [Contact Information]. Written correspondence should be sent to the New York State Department of Health.

Sincerely,

[Signature]
New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X) PROVIDER/SUPPLIER/CIA IDENTIFICATION NUMBER:  

(X) MULTIPLE CONSTRUCTION
A. BUILDING
B. WING
C. STAIR

(X) STATE SURVEY COMPLETED

04/24/2014

NAME OF PROVIDER OR SUPPLIER
STREET ADDRESS, CITY, STATE, ZIP CODE

T000

INITIAL COMMENTS

STATE FACILITY OPERATING CERTIFICATE

NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A SURVEY CONDUCTED AT THE FACILITY ON 04/21/14, 04/23/14 & 04/24/14 IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

T2023

761.2.(f) (7) ORGANIZATION AND ADMINISTRATION, Operator

The responsibilities of the operator shall include but not be limited to:
(1) ensuring that the following documents, as applicable, are retained on file in the administrative offices of the center,
(7) the applications for admission to staff privileges of all current medical and dental staff, which shall include for each applicant: a statement of training and experience, all supporting documents, satisfactory evidence of conformity with requisite professional licensing laws, and records of actions and recommendations of staff committees of the respective professional staff and of the governing authority.

Office of Health Systems Management

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

STATE FORM

Response:  

Follows all federal, New York State and local rules and regulations regarding hiring and employing individuals as documented in its policy, which is located in the personnel files. All employees of the facility are trained and experienced in providing the care for which they are privileged. Every personnel file contains all support documents, satisfactory evidence of conformity with requisite professional licensing laws, and records of actions and recommendations of staff committees of the respective professional staff and of the governing authority.  

Title:  

Americans United for Life
New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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Office of Health Systems Management
STATE FORM
This Regulation is not met as evidenced by:

Based on document review the facility failed to ensure documented evidence of conformity with the contract agreement requests that all licensed health professionals must have in accordance with the Governing Authority when performing in three (3) of three (3) Employee Contract Records (Staff Members #2, #5 and #8).

Findings:

On the afternoon of 04/21/14 a review of the personnel records between Staff Members #2, #5 and #8 noted that licensed health professionals performing must be appropriately trained, experienced, and have demonstrated skills in the provision of moderate sedation and be granted privileges to provide .

Review of the Personal Records for Staff Members #2, #5 and #8 demonstrated that all lacked evidence of these proficiencies and competencies.

These findings were confirmed with Staff #1 in the afternoon on 04/21/14.

751.6 (c) ORGANIZATION AND ADMINISTRATION. Personnel.

The operator shall ensure:

(c) that the health status of each employee is examined prior to the beginning of employment, which is sufficient in scope to ensure that the

Appropriate licensing, credentialing, immunization, and health status documents from its consultants, are (and licensed and credentialing for the work they perform at . On June 5, 2014 amended its policy to include . As of June 22, 2014 has personnel file for all . As it does for employees. The files contain all required documents including: credentialing documents, health assessment, immunization and PPD documents, and orientation and training documents.

For future , the Medical Director across all staff will have its Medical Director assess the competency of the . Competencies will be documented on a competency checklist that follows NYS and protocols. The Director of Human Resources will be responsible for monitoring the competency approval and the Senior VP for Health Services will be responsible for the entire corrective action. The Senior VP will perform a personnel file audit to ensure compliance before any new .

New York State Department of Health

T2023 Continued From page 1

T2089

Office of Health Systems Management
STATE FORM

T2089

As stated in policy, which is located in the personnel files for all employees of .

June 5, 2014

Adaptable

7/2/14

Americans United for Life
Employee is free from a health impairment which is of potential risk to patients or which may interfere with the performance of his/her duties.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that the health status of employees was examined prior to the beginning of their employment. This was evident in two (2) of three (3) Personnel Records reviewed for the Staff Members #2 and #5.

Findings:

Review of the Personnel Record for Staff #2 noted a start date of 01-27-11. The Personnel Record lacked evidence of a pre-employment health status assessment.

Review of the Personnel Record for Staff #5 indicated a start date of 01-01-11. The Personnel Record lacked evidence of a pre-employment health status assessment.

During an interview with Staff #1 on 04/21/14 at 11:00 AM, Staff #1 stated that they don't need Personnel Files for the areas the staff member stated the staff were a part of.

This finding was confirmed with Staff #1 on 04/23/14 at 2:35 PM.

As of June 5, 2014, the facility amended its policy to ensure the documentation of examination of staff members prior to employment and annually thereafter, is maintained on site.

In keeping with our policy, a checklist of all employment and annual requirements, which include health assessments (physical exams) for all staff and is completed and signed by the Director of Human Resources, and included in each individual's personnel file. This checklist is countersigned by the employee's or supervisor prior to employment.

The Director of Human Resources also ensures that all staff and are up-to-date with their annual health assessments by maintaining an on-line file of the due date of annual assessments for all staff and and emails it to the managers for follow-up with their direct reports.

This policy is in effect.
The operator shall ensure:
(d) a record of the following tests, procedures and examinations is maintained for all employees:
(1) a certificate of immunization against rubella.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that employees are immune to Rubella. This was evident in one (1) of three (3) Personnel Records reviewed for the Staff.

Findings:

A review of the Personnel Record for Staff #2 noted a start date of 01/01/11. The Personnel Record lacked evidence of immunity to Rubella.

This finding was confirmed with Staff #1 on 04/23/14 at 2:35PM.

As stated in the personnel policy, which is located in the Personnel Manual, all employees of the facility are required to submit serological proof of immunity to measles and rubella before commencement of work at the facility. Each employee has been given an opportunity to sign a statement indicating their immune status.

As of April 25, 2014, the personnel file for Staff Member #2, referred to by the DOH as ‘staff member’ #2, contained such evidence.

As of June 5, 2014, the personnel file for Staff Member #2, contained such evidence.

As of June 5, 2014, the facility extended the above-mentioned policy to include certificates of immunity on all personal files are maintained on site and contain evidence of rubella immunization or testers documenting immunity through the following process:

- Utilizes a checklist for each new employee that lists all pre-employment requirements, including evidence of immunity to Rubella. The Director of Human Resources is responsible for reviewing personnel files prior to patient contact to make sure all requirements have been met. This checklist is counter-signed by the employee's or contract worker's supervisor prior to employment.

The Director will monitor this process and the Senior VP for Health Services will monitor the entire plan.

This policy is in effect.
Continued From page 4

measles for all personnel born on or after January 1, 1957.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that employees are immune to measles. This was evident in one (1) of three (3) Personnel Records reviewed for the

(Staff #2).

Findings:

A review of the Personnel Record for Staff #2 documented a start date of 01/11. The Personnel Record lacked evidence of immunity to measles.

During an interview with Staff #1 on 04/21/14 at 11:00AM, Staff #1 stated that they don't need Personnel Records for the

The staff member stated the

This finding was confirmed with Staff #1 on 04/23/14 at 2:35PM.

12096

751.6 (d) 4 ORGANIZATION AND ADMINISTRATION Personnel.

The operators shall ensure:

(d) that a record of the following tests, procedures and examinations is maintained for all

2014
T2096  Continued From page 5

(4) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, either tuberculin skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection, prior to employment or affiliation and no less than every year thereafter for negative findings. Positive findings shall require appropriate clinical follow-up but no repeat tuberculin skin test or blood assay. The medical staff shall develop and implement policies regarding positive outcomes.

This Regulation is not met as evidenced by:

- Based on record review and staff interview, the facility failed to ensure that employees prior to employment, and annually thereafter, are tested for the Tuberculin infection. This was evident in one (1) of nine (9) Personnel Records reviewed (Staff #2).

Findings:

A review of the Personal Record for Staff #2 noted a start date of 03/01/11. The Personnel Record lacked evidence of this employee’s pre-employment Tuberculin infection status and annually thereafter.

During an interview with Staff #1 on 04/21/14 at 11:00AM, she stated they don’t need Personnel Files for the staff. The staff member stated...
**T2096** Continued From page 6

This finding was confirmed with Staff #1 on 04/23/14 at 2:35 PM.

**T2097** 751.5 (d) (5) ORGANIZATION AND ADMINISTRATION: Personnel

The operator shall ensure:

(d) that a record of the following tests, procedures and examinations is maintained for all employees:

(5) an annual, or more frequent if necessary, health status reassessment to assure freedom from a health impairment which is a potential risk to the patients or might interfere with the performance of duties.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that employees received an annual health status reassessment. This was evident in one (1) of three (3) Personnel Records of the [REDACTED] reviewed (Staff #2).

Findings:

A review of the Personnel Record for Staff #2 noted a start date of 01/01/11. The Personnel Record lacked evidence of an annual health status reassessment.

**T2098**

Response:

As stated in the [REDACTED] policy located in the [REDACTED] all employees must submit a completed [REDACTED] to the Human Resources Department annually within one month of their anniversary date that assures that the employee is in good physical and mental health and is cleared to continue working at this location.

As of April 2014, the personnel file for [REDACTED] referred to by the DOH as "staff member," #2, contained such evidence.

As of June 5, 2014, [REDACTED] amended the above-mentioned policy to include [REDACTED].

To ensure compliance with this policy, [REDACTED] Director of Human Resources maintains a grid that lists all staff and [REDACTED] and the date of their annual health assessment is due. This grid is reviewed monthly by Managers who, in turn, advise their staff members (face-to-face and through email) one month prior to when their health assessment is due. In addition, compliance with this policy is reviewed quarterly by [REDACTED].

This policy is in effect.
During an interview with Staff #1 on 04/21/14 at 11:00AM, Staff #1 stated that they don't need Personnel Files for the facility.

This finding was confirmed with Staff #1 on 04/23/14 at 2:35PM.

C: (c) that a personnel file is maintained for each employee.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to maintain Employee Files for the facility.

This was evident for three (3) of three (3) C, (Staff Members #2, #5 and #9).

Findings:

During an interview with Staff #1 on 04/21/14 at 11:00AM she stated that they don't need Personnel and Credential Files for the facility.

No Personnel Files were provided on 04/21/14.
T2098 Continued From page 8

Personnel Files were provided for Staff Members #2, #5, and #6 on 04/23/14 and 04/24/14; however, the files were incomplete.

Please refer to the findings noted under Tags T2013, T2089, T2091, T2093, T2096, and T2097.

T2103 751.6 (g) ORGANIZATION AND ADMINISTRATION Personnel

The operator shall ensure:
(1) the assignment of duties and functions to each employee that are commensurate with his/her license, registration and/or certification, and experience and competence.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure confirmation of the employees' training, experience, references, competencies, delineation of privileges and performance evaluations. This was evident in four (4) of nine (9) Personnel Records reviewed (Staff Members #2, #5, #8 and #9).

Findings:

A review of the Personnel Record for Staff #2 noted a start date of 01/17/11. The Personnel Record lacked evidence of confirmation of the employee's training, experience, references, competencies, delineation of privileges and performance evaluations.

A review of the Personnel Record for Staff #5
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Office of Health Systems Management:
STATE FORM

Americans United for Life
T2103 Continued From page 9

The Personnel Record lacked evidence of confirmation of the employee's training, experience, references, competencies, delineation of privileges and performance evaluations.

A review of the Personnel Record for Staff #8 noted a start date of 01/11. The Personnel Record lacked evidence of confirmation of the employee's training, experience, references, competencies, delineation of privileges and performance evaluations.

Similar findings were found on review of the Personnel Record for Staff #9.

During an interview with Staff #1 on 04/21/14 at 11:00 AM, Staff #1 stated that they don't need Credential Files for the [redacted] Staff Members #2, #5 and #9. The staff member stated the [redacted] to

These findings were confirmed with Staff #1 on 04/23/14 at 12:35 PM.

T2106 751.6 (j) ORGANIZATION AND ADMINISTRATION, Personnel

The operator shall ensure:

(j) that each new employee is provided with a planned orientation to the center's operation and personnel policies.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the

Response:

As documented in its [redacted] policy which is located in the [redacted] conducts a mandatory orientation for all new staff and volunteers on a monthly basis. During initial training staff and volunteers learn about the departments in which they work.

As of June 014, [redacted] has amended its policy to include [redacted] workers in its contract. [redacted] received individual orientation prior to providing [redacted]. Going forward, [redacted] workers will attend [redacted] mandatory
T2106

Continued From page 10

facility failed to provide evidence of the employees' orientation to the Center's operations and policies. This was evident in four (4) of nine (9) Staff Members #2, #5, #8 and #9 Personnel Files.

Findings:

During an interview with Staff #1 on 04/21/14 at 11:00AM, Staff #1 stated that they don't need Personnel Files for the [Staff Members #2, #5 and #8]. The staff member stated, 

Review of the Personnel Record for Staff #2 noted a start date of 01/11. The Personnel Record lacked documented evidence of orientation to the facility.

Review of the Personnel Record for Staff #5 noted a start date of 01/11. The Personnel Record lacked documented evidence of orientation to the facility.

Review of the Personnel Record for Staff #6 noted a start date of 01/11. The Personnel Record lacked documented evidence of orientation to the facility.

Review of the Personnel Record for Staff #7 noted a start date of 08/13. The Personnel Record lacked documented evidence of orientation to the facility.

These findings were confirmed with Staff #1 on 04/23/14 at 2:35PM.

T2106

Orientation, which will be documented in the personnel file.

In keeping with our policy, a checklist of all pre-employment requirements, including orientation to operation and personnel policies, will be completed by the Director of Human Resources who is responsible for monitoring this policy. Compliance with this policy is reviewed quarterly by the Risk Management program.

This policy is in effect.
Findings:

Record review for Patient #1 revealed that on 03/14, the patient had a procedure. The patient's signature dated 03/14 and the signature of the witness who is the patient's mother dated 03/14. The patient attested that the client got this information. She said she read and understood it. She was able to ask any questions she had.

Record review for Patient #2 revealed that on 03/14 the patient had a procedure. The patient documented the patients and (witness's) signatures dated 03/14.

Record review for Patient #3 revealed that on 12/13 the patient had a procedure. The patient's signature dated 12/13. (Witness's) signatures dated 12/13.

An interview with Staff #1 on the date of 04/14 revealed that the (witness) gives the patient during the testing. The staff recons the patient for the patient. The staff receives special training to perform this function.

Review of the facility's policy titled dated 2012, documented that clinicians performing surgical abortions must ascertain that informed consent has been obtained before providing the abortion.

There was no documented evidence that the

Office of Health Systems Management
STATE FORM

Americans United for Life
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<tr>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Summary Statement of Deficiencies</th>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Provider's Plan of Correction</th>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Complete Date</th>
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</table>

New York State Department of Health

Statement of Deficiencies and Plan of Correction

(X) Provider/Supplier/CUA Identification Number

(01) Multiple Construction

A Building

B Wing

04/24/2014

Name of Provider or Supplier

Street Address, City, State, Zip Code

Office of Health Systems Management

State Form

Americans United for Life
Physician/Surgeon discussed the surgical risks, benefits, and alternatives with the patient prior to surgery as required.

Similar findings were noted in the Medical Record for Patient #8.

755.4(b) FREE STANDING AMBULATORY SURGERY SERVICES.

Anesthesia services.
  The operator shall ensure that:
  (b) administration of anesthesia is in accordance with current standards of professional practice.

This Regulation is not met as evidenced by:

Based on record review and staff interview, it was determined that the facility failed to ensure the dosage and route of administration of the anesthetics and/or the time the intraoperative vital signs were documented for four (4) of four (4) records reviewed (Patients #1, #2, #3 and #8).

Findings:

Record review for Patient #1 revealed that on March 14, 2014 that the patient had a [Redacted] procedure. [Redacted] surgery was started.

All the CRNA’s (Certified Registered Nurse Anesthetist) documented a dose of [Redacted] given. The dosage and route of the medications were not documented.

Response:

[Redacted] currently documents the dosage and route of administration of all administered to patients. Using one of the examples given, [Redacted] will document the dosage and route of administration with an expanded description as of June 16, 2014. The above example will now read as follows: [Redacted] given.

Additionally, [Redacted] will have the CRNA take a stamp the intra-operative vital signs beginning June 16, 2014. To ensure compliance, [Redacted] will review all abortion records for the next three months. Semi-annual audits will be performed subsequently to assure continued compliance.

All CRNA’s were notified of this change through email on June 16, 2014 and face to face conversation with the Senior VP for Health Services. The CRNA’s were educated by the Senior VP for Health Services on the importance of signing their notes at the beginning, intraoperatively and at the end of all procedures. The Senior VP began auditing this process to ensure compliance and will continue to do so for the next six months and then semi-annually.

The findings of the audits will be reported to the CRNAs and PPNC’s Risk Management Patient Services Work group.

This policy is in effect.
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<tr>
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<th>TAG</th>
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</thead>
<tbody>
<tr>
<td>T2677</td>
<td>Continued From page 14</td>
<td></td>
<td>T2677</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The following documentation related to patient care was not found: blood pressure, pulse, respiratory rate, and level of consciousness. The above notations were not timed.

Record review for Patient #2 revealed that on 02/14/14 the patient had a procedure. At the time, [redacted] was started.

At [redacted], the CRNA's Note documented a dose of [redacted] given. The dosage and route of the medications were not documented.

Record review for Patient #3 revealed that on 02/13/14 the patient had a procedure. At the time, surgery was started.

The CRNA's Note documented a dose of [redacted] given. The dosage and route of the medications were not documented.

The Intraoperative Vital Signs Note documented blood pressure, pulse, respiratory rate, and level of consciousness. The above notations were not timed.

Review of the Medical Record for Patient #8 documented similar findings.
755.6 (d) FREE-STANDING AMBULATORY SURGERY SERVICES.

Patient admission and discharge.
The operator shall ensure that:
(d) each patient is evaluated by a physician for proper anesthesia recovery, and discharged upon the written order of a physician.

This Regulation is not met as evidenced by

Based on record review and staff interview, it was determined that the facility failed to ensure that the Physician ordered the discharge after assessing the patient's recovery from the procedure in accordance with the protocol located in the Medical Protocol book. "Licensed health professionals supervising the recovery area for [redacted] MUST be:
- trained in the management of the recovery area
- currently certified in CPR/ALS
- immediately available and remain on the premises until all clients have been discharged
- able to implement an emergency protocol and direct and assist with CPR until outside assistance is obtained, and

MUST not:
- have duties other than client recovery or have any tasks that would interrupt or compromise the continuous observation and monitoring of recovering clients
- leave the client unattended until the client(s) is discharged."

As of June 5, 2014, the protocol has been amended to include, "each patient must be evaluated by the physician for proper recovery, and discharged upon the written order of the physician." Each physician providing abortion services at [redacted] will receive notice of this change from the Medical Director on June 16, 2014 and will be required to discharge the patient from recovery when she has had proper abortion recovery.

To ensure compliance, the Senior VP for Health Services will review all abortion records for

Office of Health Systems Management
STATE FORM

<table>
<thead>
<tr>
<th>ID</th>
<th>TAG</th>
<th>PROFESSIONAL PLAN OF CORRECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2803</td>
<td></td>
<td>as always had Certified Registered Nurse Anesthetists, as well as staff who have been specifically trained to assist the physician in our procedure room; moreover, has registered nurses in its recovery room.</td>
</tr>
<tr>
<td>T2803</td>
<td></td>
<td>has already begun recruiting an RN to work in the procedure room; the Director of Human Resources will seek to fill this position by September 1, 2014.</td>
</tr>
<tr>
<td>T2803</td>
<td></td>
<td>Until an RN is hired, will staff the procedure room with temporary staff beginning August 2, 2014.</td>
</tr>
</tbody>
</table>

**Findings:**

There is no licensed Nurse in the PR during the procedure. The form documents the staff that is assigned to work in the PR.

**Review of the Form:**

- Form between 09/13/04 documented the staff assigned to the PR.
- Record review for Patient #1 revealed that on 08/14 the patient had a procedure. Staff #2 administered the and Staff #3 performed the procedure.
- Form dated 03/14 revealed Staff #4 was assigned to the PR.
- Record review for Patient #5 revealed that on 02/14 the patient had a procedure. Staff #5 administered the and Staff #6 performed the procedure.
<table>
<thead>
<tr>
<th>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</th>
<th>PROVIDER/SUPPLIER/CQA IDENTIFICATION NUMBER</th>
<th>MULTIPLE CONSTRUCTION</th>
<th>DATE SURVEY COMPLETED</th>
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</thead>
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<td>Xi</td>
<td>Xi</td>
<td>04/24/2014</td>
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</table>

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<tr>
<th>NAME OF PROVIDER OR SUPPLIER</th>
<th>STREET ADDRESS, CITY, STATE, ZIP CODE</th>
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<table>
<thead>
<tr>
<th>Prefix</th>
<th>Tag</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH corrective action should be cross-referenced to the appropriate deficiency)</th>
<th>Complete Date</th>
</tr>
</thead>
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Office of Health Systems Management
STATE FORM

Americans United for Life
Review of the "Center Assistant Weekly Schedule" form dated 02/14 revealed Staff #7 was assigned to the PR.

Record review for Patient #7 revealed that on 03/14 the patient had a [redacted] procedure.

Staff #5 administered the [redacted] and Staff #6 performed the procedure.

Review of the "Center Assistant Weekly Schedule" form dated 05/14 revealed Staff #7 was assigned to the PR.

Review of the Medical Record documented similar findings for Patient #4.

---

T2803

756.6 ABORTION SERVICES Quality Assurance

In addition to the requirements set forth in Section 751.8 of this Title, the operator shall ensure that there is a review of any abortion procedure completion with the use of these findings in the development and revision of policies and in consideration of renewing or granting staff privileges.

This Regulation is not met as evidenced by:

---

Response:

June 5, 2014
<table>
<thead>
<tr>
<th>OX1 Tag</th>
<th>Provider's Plan of Correction (Each corrective action should be cross-referenced to the appropriate deficiency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continued From page 19</td>
<td></td>
</tr>
</tbody>
</table>

Findings:

To ensure compliance with this policy, the Senior VP for Patient Services will review every incident that requires the Medical Director's review; the findings of these audits will be reported to the Risk Management Patient Services Work group for any corrective action needed.

This policy is in effect.

Office of Health Systems Management

STATE FORM
July 10, 2014

Re: Article 28 Survey

Dear [Redacted]

Your Plan of Correction submitted on June 17, 2014 in response to our Article 28 Survey has been reviewed by the Department.

Based on this review, the Department concurs that Regulation 756.5 (c), Tag T2803, is the requirement which is applicable to the procedures performed in your facility. Therefore Regulation 756.5 (g), Tag T2807, has been rescinded, Tag T2803 has been added, and a new Statement of Deficiencies (CMS-2567) with this revision is attached.

The items which have been found to be unacceptable are stated in the attached report.

Please submit a revised Plan of Correction. The Plan of Correction should be generic for each deficiency, as well as case specific, and be preventive in nature to aim at eliminating such deficiencies in the future. The Plan is to include specific corrective actions, title of the party responsible for each corrective action, and a completion date for each action plan. Clearly identify, by tag number, the citation being addressed.

If implementation of the Plan of Correction is delayed for any reason, the facility must provide an interim plan until the full corrective action plan is put into effect. Failure to provide any of the foregoing required information constitutes an unacceptable response. Please make certain that the first page of the Plan of Correction is signed and dated by a duly authorized representative of your facility.

Your Plan of Correction must be submitted to this office by July 24, 2014.
Should you have any questions you may contact this office at [redacted]. Written correspondence should be sent to the [redacted].

Sincerely,

[Signature]

[Amber Teens United for Life logo]
UNACCEPTABLE PLAN OF CORRECTION (POC) REVIEW FORM

Facility Name: [REDACTED]
Type of Survey: Re-Licensure  Complaint #: N/A
Event ID #: [REDACTED]  Date(s) of Survey: 04/21/14, 04/23/14 & 04/24/14

The facility's Plan of Correction (POC) has been reviewed and found acceptable with the following exceptions:

<table>
<thead>
<tr>
<th>Deficiency #</th>
<th>The POC Lacks The Required Facility Action</th>
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</thead>
<tbody>
<tr>
<td>T2023</td>
<td>The corrective action plan fails to ensure that future staff [REDACTED] will have competency in [REDACTED] how this will be documented, a staff member responsible to review and approve the staff competency, a staff member responsible for monitoring, and the method and staff member responsible for the entire corrective action.</td>
</tr>
<tr>
<td>T2089</td>
<td>The plan lacks a system correction, how the facility will ensure implementation of the policy, who will do the reviews, how the facility will monitor to ensure that all staff have pre-employment PE (physical exam), a responsible staff member and the completion date.</td>
</tr>
<tr>
<td>T2091</td>
<td>The plan lacks a system to implement the amended policy, who is responsible to review the files prior to patient contact and approves staff, monitoring, a responsible staff member for the entire plan and the completion date.</td>
</tr>
<tr>
<td>T2093</td>
<td>Same as T2091.</td>
</tr>
<tr>
<td>T2096</td>
<td>The same issues as identified for T2091 and T2093 but since PPDs are required annually, the facility needs a system to alert and obtain evidence that staff meet the requirement and monitoring of staff compliance by the facility.</td>
</tr>
</tbody>
</table>
The facility's Plan of Correction (POC) has been reviewed and found acceptable with the following exceptions:

<table>
<thead>
<tr>
<th>Deficiency #</th>
<th>The POC Lacks The Required Facility Action</th>
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</thead>
<tbody>
<tr>
<td>T2097</td>
<td>The corrective action plan lacks how the facility will ensure that staff receive and complete the annual health assessment form, how staff will be notified one (1) month prior, by whom, who will monitor compliance, a responsible staff member and the completion date.</td>
</tr>
<tr>
<td>T2098</td>
<td>The facility failed to develop a correction plan showing who is responsible for establishing and maintaining personnel files, ensuring staff have been in-serviced, who will monitor the plan and the completion date.</td>
</tr>
<tr>
<td>T2103</td>
<td>The plan lacks a responsible staff member for maintaining this documentation, tracking of information, monitoring files for compliance and the completion date.</td>
</tr>
<tr>
<td>T2106</td>
<td>The plan lacks a corrective action for future staff, a monitoring plan, a responsible staff member and the completion date.</td>
</tr>
<tr>
<td>T2178</td>
<td>The plan lacks a responsible staff member and the completion date.</td>
</tr>
</tbody>
</table>
The facility's Plan of Correction (POC) has been reviewed and found acceptable with the following exceptions:

<table>
<thead>
<tr>
<th>Deficiency #</th>
<th>The POC Lacks The Required Facility Action</th>
</tr>
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<tbody>
<tr>
<td>T2677</td>
<td>The plan lacks staff education, a specific monitoring plan, a responsible staff member and the completion date.</td>
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<tr>
<td>Free-Standing</td>
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<tr>
<td>Ambulatory Surgery</td>
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<tr>
<td>Services-Anesthesia</td>
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<tr>
<td>Services</td>
<td></td>
</tr>
<tr>
<td>756.1 (a)</td>
<td>General Requirements</td>
</tr>
<tr>
<td>T2699</td>
<td>The plan lacks a detailed auditing plan, a responsible staff member, the completion date and reporting to QAPI (Quality Assurance Performance Improvement).</td>
</tr>
<tr>
<td>Free-Standing</td>
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<tr>
<td>Ambulatory Surgery</td>
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<tr>
<td>Services-Patient</td>
<td></td>
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<tr>
<td>Admission and Discharge</td>
<td></td>
</tr>
<tr>
<td>756.1 (a)</td>
<td>General Requirements</td>
</tr>
<tr>
<td>T2807</td>
<td>Citation rescinded. The correct citation 756.5(c) will be issued (T2803). The use of a CRNA as the licensed nurse present during procedures does not meet the minimum requirement. The CRNA is acting as the anesthetist and therefore cannot perform the role of the nurse present in the room as well, especially in an emergency. The presence of &quot;other trained staff&quot; does not meet the requirement.</td>
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<tr>
<td>Abortion Services-</td>
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<tr>
<td>Nursing Services</td>
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<tr>
<td>T2810</td>
<td></td>
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<tr>
<td>Abortion Services-</td>
<td></td>
</tr>
<tr>
<td>Quality Assurance</td>
<td></td>
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</table>
STATE FAC ID: [REDACTED]
OPERATING CERTIFICATE #: [REDACTED]

NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10 NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A SURVEY CONDUCTED AT THE FACILITY ON 04/21/14, 04/22/14 & 04/24/14 IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

T2023 761 2(?) ORGANIZATION AND ADMINISTRATION, Operator

The responsibilities of the operator shall include but not be limited to:
(1) ensuring that the following documents, as applicable, are retained on file in the administrative offices of the center:
(7) the applications for admission to staff privileges of all current medical and dental staff, which shall include for each applicant: a statement of training and experience, all supporting documents, satisfactory evidence of conformity with requisite professional licensing laws and records of actions and recommendations of staff committees of the respective professional staff and of the governing authority.

Office of Health Systems Management
LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

STATE FORM

[REDACTED]

[REDACTED]
<table>
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<tr>
<th>Name of Provider or Supplier</th>
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<tr>
<th>Summary Statement of Deficiencies</th>
<th>Providers' Plan of Correction</th>
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<tbody>
<tr>
<td>(Each deficiency must be preceded by full regulatory or license identifying information)</td>
<td>(Each corrective action should be cross-referenced to the appropriate deficiency)</td>
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<th>Date Survey Completed</th>
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<td>04/24/2014</td>
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Office of Health Systems Management
STATE FORM

Americans United for Life

New York State Department of Health
This Regulation is not met as evidenced by:

Based on document review the facility failed to ensure documented evidence of conformity with the contract agreement requires that all licensed health professionals must have in accordance with the governing authority when performing [REDACTED] in three (3) of three (3) Employee Contract Records (Staff Members #2, #5 and #6).

Findings:

On the afternoon of 04/21/14 a review of the [REDACTED] document titled [REDACTED] between [REDACTED] and Staff Members #2, #5 and #6 noted that [REDACTED] must be appropriately trained, experienced, and have demonstrated skills in the provision of medication selection and be granted privileges to provide [REDACTED]

Review of the Personnel Records for Staff Members #2, #5 and #6 demonstrated that all lacked evidence of these proficiencies and competencies.

These findings were confirmed with Staff #1 in the afternoon on 04/21/14.

751.6(c) ORGANIZATION AND T2099 ADMINISTRATION Personnel.

The operator shall ensure.

c) that the health status of each employee is examined prior to the beginning of employment, which is sufficient in scope to ensure that the

[REDACTED] follow(s) all federal, New York State and rules and regulations regarding hiring and employing individuals as documented in its [REDACTED] which is located in the [REDACTED]. All employees or are trained and experienced in providing the care for which they are privileged. Every person file contains all supporting documents, satisfactory evidence of conformity with requisite professional licensing laws, and records of actions and recommendations of staff committee of the respective professional staff and of the governing authority. [REDACTED] consultants have Letters of Agreement on file that require them to be trained and experienced in providing the care for which they are contracted. Upon agreement [REDACTED] obtains the appropriate licensing, credentialing, immunization, and health status documents from the [REDACTED] contractors are (and have been since contracting with [REDACTED] licensed and credentialed for the work they perform at [REDACTED] On June 15, 2014 amended its policy to include, As of April 22, 2014, [REDACTED] has personnel files for all personnel as it does for employees. The files contain all required documents including licensing and credentialing documents, health assessment, immunization and PPD documents, and orientation and training documents. As of April 28, 2014, personnel files for [REDACTED] referred to by the DOH as "[REDACTED]" and #5 and #6 contained all supporting documents.
T2089  Continued From page 2

employee is free from a health impairment which is of potential risk to patients or which may interfere with the performance of his/her duties.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that the health status of employees was examined prior to the beginning of their employment. This was evident in two (2)
of three (3) Personnel Records reviewed for the Staff Members #2 and #5.

Findings:

Review of the Personnel Record for Staff #2 noted a start date of 01-11. The Personnel Record lacked evidence of a pre-employment health status assessment.

Review of the Personnel Record for Staff #6 indicated a start date of 01-11. The Personnel Record lacked evidence of a pre-employment health status assessment.

During an interview with Staff #1 on 04/21/14 at 11:00AM, Staff #1 stated that the item was not completed.

This finding was confirmed with Staff #1 on 04/23/14 at 2:35PM.

T2089  Response:

As stated in the [redacted] policy, which is located in the Personnel Files of all employees of [redacted]. Staff Members #2, #5 and #6 were examined prior to the beginning of employment to ensure that the employee is free from a health impairment which is of potential risk to patients or which may interfere with the performance of his/her duties. Documentation of this examination is included in their on-site personal files.

[Redacted] referred to by the DOH as 'staff members' #2, #5 and #6 are (and were) free from such health impairments. As of June 6, 2014, [redacted] amended its policy to ensure that documentation of examination of staff are maintained on site. As of 6/2014, personal files for [redacted] contained such evidence.
<table>
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<tr>
<th>T2091</th>
<th>Continued From page 3</th>
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<tbody>
<tr>
<td>T2091</td>
<td>751.6 (d) (1) ORGANIZATION AND ADMINISTRATION: Personnel.</td>
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<tr>
<td></td>
<td>The operator shall ensure:</td>
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<td></td>
<td>(d) that a record of the following tests,</td>
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<tr>
<td></td>
<td>procedures and examinations is maintained for all</td>
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<tr>
<td></td>
<td>employees:</td>
</tr>
<tr>
<td></td>
<td>(2) a certificate of immunization against rubella.</td>
</tr>
</tbody>
</table>

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that employees are immune to Rubella. This was evident in one of three Personnel Records reviewed for this staff (Staff #2).

Findings:

A review of the Personnel Record for Staff #2 noted a start date of 01/11. The Personnel Record lacked evidence of immunity to Rubella.

This finding was confirmed with Staff #1 on 04/23/14 at 2:35PM.

751.8 (d) (2) ORGANIZATION AND ADMINISTRATION: Personnel.

The operator shall ensure:

(d) that a record of the following tests, procedures and examinations is maintained for all employees:

(2) a certificate of immunization against rubella.

<table>
<thead>
<tr>
<th>T2091</th>
<th>Response:</th>
</tr>
</thead>
</table>
|     | As stated in [redacted], policy which is located in the personnel file of the employees of [redacted]. All employees of [redacted] must have a record of immunization against rubella in their personnel files. Each employee must have a record of immunization against rubella and has been since contracting with the facility. As of [redacted], the facility has amended its policy to include contract workers. Files will be maintained on site and contain evidence of immunization or letters documenting immunity. As of [redacted], the personnel file for [redacted] contained such evidence.
**New York State Department of Health**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(x) PROVIDER/SupPLIER/MA IDENTIFICATION NUMBER</th>
<th>(x) MULTIPLE CONSTRUCTION</th>
<th>(x) DATE SURVEY COMPLETED</th>
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<td></td>
<td>04/24/2014</td>
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**NAME OF PROVIDER OR SUPPLIER**

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<tr>
<th>STREET ADDRESS</th>
<th>CITY, STATE ZIP CODE</th>
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**T2093** Continued From page 4

measures, for all personnel born on or after January 1, 1957.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that employees are immune to ____________ as was evident in one (1) of three (3) Personnel Records reviewed for the (Staff #2).

**Findings:**

A review of the Personnel Records for Staff #2 documented a birth date of 01/19/11. The Personnel Record lacked evidence of immunity to

During an interview with Staff #1 on 04/21/14 at 11:30AM, Staff #1 stated that they don't need

This finding was confirmed with Staff #1 on 04/23/14 at 2:35PM.

**751.5 (d) (4) ORGANIZATION AND ADMINISTRATION. Personnel**

**T2095** The operator shall ensure:

(d) that a record of the following tests, procedures and examinations is maintained for all employees:
T2096  Continued From page 5

(4) for all personnel prior to employment or affiliation, except for personnel with no clinical or patient contact responsibilities who are located in a building or site with no patient care services, either tuberculosis skin test or Food and Drug Administration (FDA) approved blood assay for the detection of latent tuberculosis infection, prior to employment or affiliation and no less than every three years thereafter for negative findings. Positive findings shall require appropriate medical follow-up but no repeat tuberculosis skin test or blood assay. The medical staff shall develop and implement policies regarding positive outcomes.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure that employees prior to employment and annually thereafter, are tested for the Tuberculosis infection. This was evident in one (1) of three (3) Personnel Records reviewed for the

Findings:

A review of the Personnel Record for Staff #2 noted a start date of 06/11. The Personnel Record lacked evidence of this employee's pre employment Tuberculosis infection status and annually thereafter.

During an interview with Staff #1 on 04/21/14 at 11:00AM, she stated they don't need Personnel Files for the. The staff member stated

Response:

As stated in. the policy located in the.

[Redacted] all employees of.

have evidence of a post Mantoux test submitted to Human Resources before any employee begins working at.

Each employee (and has had since contracting with) has evidence of a post Mantoux test. As of December 2014 policy includes contract workers as well as employees, and states that consultant personnel files will contain evidence of initial and annual testing for the Tuberculous infection. As of April 24, 2014 the personnel file for.

[Redacted] referred to by the DOH as staff member, #2, contained such evidence.
<table>
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<tr>
<th>Statement of Deficiencies and Plan of Correction</th>
<th>Provider/Supplier/Owner Identification Number</th>
<th>Date Survey Completed</th>
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<td>STREET ADDRESS, CITY, STATE, ZIP CODE</td>
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| David F. Smith | 123 Main St, Anytown, NY 12345 | |

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<td>EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LICIDENTIFYING INFORMATION</td>
<td>EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY</td>
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Office of Health Systems Management
STATE FORM

Americans United for Life
This finding was confirmed with Staff #1 on
04/23/14 at 2:35PM.

751.6 (d) (5) ORGANIZATION AND
ADMINISTRATION, Personnel.

The operator shall ensure:
(d) that a record of the following tests,
procedures and examinations is maintained for all
employees.
(5) an annual, or more frequent if necessary,
health status reassessment to assure freedom
from a health impairment which is a potential risk
to the patients or might interfere with the
performance of duties.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the
facility failed to ensure that employee received
an annual health status reassessment. This was
evident in one (1) of three (3) Personnel Records
of the [redacted] reviewed (Staff #2).

Findings:

A review of the Personnel Record for Staff #2
noted a start date of 01/01/11. The Personnel
Record lacked evidence of an annual health
status reassessment.

During an interview with Staff #1 on 04/21/14 at
11:00AM, Staff #1 stated that they did not need
Personnel Files for the [redacted] the staff

Response:

[Redacted] policy.

As stated in the [redacted] of [redacted], a completed
form to the Human Resources Department annually within
one month of their anniversary date that assures
that the employee is in good physical and mental
health and is cleared to continue working at
[redacted]. As of June 2014, [redacted] amended its
policy to include contract workers and will
include in contract personnel files, evidence of
an annual health assessment to assure freedom
from a health impairment which is a potential risk
to the patients or might interfere with the
performance of duties. As of April 22, 2014, the
personnel file for [redacted] referred to by the DOH as "staff member," #2,
contained such evidence.
This finding was confirmed with Staff #1 on 04/23/14 at 2:35PM.

751.5(e) ORGANIZATION AND ADMINISTRATION. Personnel.

The operator shall ensure:
(c) that a personnel file is maintained for each employee.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to maintain Employee Files for the CRNAs (Certified Registered Nurse Anesthetists). This was evident for three (3) of three (3) CRNAs (Staff Members #2, #5 and #8).

Findings:

During an interview with Staff #1 on 04/21/14 at 11:00AM site stated that they do not need the CRNA's personnel files. As shown in a previous meeting they were not aware of the need to maintain personnel files for the CRNAs.

No Personnel Files were provided on 04/21/14.

Personnel Files were provided for Staff Members #2, #5 and #8 on 04/23/14 and 04/24/14, however, the files were incomplete.

Response:

The facility maintains personnel files for all employees. As of 04/22/2014 personnel files for the CRNAs were provided on site.

Staff #2, #5 and #8 are being maintained on site as of April 22, 2014.
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<td>(X4) ID PRECINCT TAG</td>
<td>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
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<td>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
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Office of Health Systems Management
STATE FORM

Americans United for Life
Please refer to the findings noted under tags T2013, T2099, T2091, T2093, T2096 and T2097.

751.6 (g) ORGANIZATION AND ADMINISTRATION Personnel

The operator shall ensure:

(g) the assignment of duties and functions to each employee that are commensurate with his/her licensure, registration and/or certification, and experience and competence.

This Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to ensure confirmation of the employees' training, experience, references, competencies, delineation of privileges and performance evaluations. This was evident in four (4) of nine (9) Personnel Records reviewed (Staff Members #2, #5, #8 and #9).

Findings:

A review of the Personnel Record for Staff #2 noted a start date of 01/1/11. The Personnel Record lacked evidence of confirmation of the employee's training, experience, references, competencies, delineation of privileges and performance evaluations.

A review of the Personnel Record for Staff #5 noted a start date of 01/1/11. The Personnel Record lacked evidence of confirmation of the employee's training, experience, references, competencies, delineation of privileges and performance evaluations.

As stated, [redacted] Health Systems Management confirmed all employees' training, experience, references, competencies and delineation of privileges before hire. [redacted] confirmed the training, experience, references, competencies and delineation of privileges before hiring. As of June 30, 2014, [redacted] amended its policy to include contract workers and going forward will keep this documentation in the personal files of new contracts. By June 30, 2014, [redacted] will also create a profile to have on file that will be completed by the staffing agency that supplies our contract RNs; this profile will detail the nurse's training, experience, references, competencies and delineation of privileges.
performance evaluations.

A review of the Personnel Record for Staff #8 noted a start date of 01/1/12. The Personnel Record lacked evidence of confirmation of the employee's training, experience, references, competencies, delineation of privileges and performance evaluations.

Similar findings were found on review of the Personnel Record for Staff #9.

During an interview with Staff #1 on 04/21/14 at 11:00AM, Staff #1 stated that they don't need Credential Files for the Staff Members.

These findings were confirmed with Staff #1 on 04/23/14 at 2:35PM.

72106 751.6(j) ORGANIZATION AND ADMINISTRATION. Personnel

The operator shall ensure:

(j) that each new employee is provided with a planned orientation to the center's operation and personnel policies.

The Regulation is not met as evidenced by:

Based on record review and staff interview, the facility failed to provide evidence of the employees' orientation to the Center's operations and policies. This was evident in four (4) of nine (9) (Staff Members #2, #5, #8 and #9) Personnel...
Findings:

During an interview with Staff #1 on 04/21/14 at 11:00 AM, Staff #1 stated that they don't need Orientation File for the Staff Members #2, #5 and

Review of the Personnel Record for Staff #2 noted a start date of 01-1-11. The Personnel Record lacked documented evidence of orientation to the facility.

Review of the Personnel Record for Staff #5 noted a start date of 01-1-11. The Personnel Record lacked documented evidence of orientation to the facility.

Review of the Personnel Record for Staff #5 noted a start date of 01-1-11. The Personnel Record lacked documented evidence of orientation to the facility.

Review of the Personnel Record for Staff #5 noted a start date of 08-1-13. The Personnel Record lacked documented evidence of orientation to the facility.

These findings were confirmed with Staff #1 on 04/23/14 at 2:33 PM.

T210d 751.9 (h) ORGANIZATION AND ADMINISTRATION.

Patients' rights.
<table>
<thead>
<tr>
<th>Statement of Deficiencies and Plan of Correction</th>
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<td>(1) Provider/Supplier/Agency Identification Number</td>
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<td>(2) Multiple Construction</td>
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<th>Name of Provider or Supplier</th>
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<td>Street Address, City, State, Zip Code</td>
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| (X) NO |
| PREMIX |
| TAG |
| Summary Statement of Deficiencies |
| Each deficiency must be preceded by full regulatory (or) title identifying information |

| (X) |
| PREMIX |
| TAG |
| Provider's Plan of Correction |
| Each corrective action should be cross-referenced to the appropriate deficiency |

| (X) |
| Complete Date |

Office of Health Systems Management
STATE FORM
Policies and procedures shall be developed and implemented regarding the patients' rights. The operator shall have in effect a written statement of patients' rights which is prominently posted in patient care areas and a copy of which is given to the patient. Such statement shall include the patients' rights to:

(5) receive from his/her physician information necessary to give informed consent prior to the start of any nonemergency procedure or treatment or both. An informed consent shall include, as a minimum, the provision of information concerning the specific procedure or treatment or both, the reasonably foreseeable risks involved, and alternatives for care or treatment, if any, as a reasonable medical practitioner under similar circumstances would disclose in a manner permitting the patient to make a knowledgeable decision.

This Regulation is not met as evidenced by:

Based on record review and staff interview, it was determined that the facility failed to ensure that the Physician/Surgeon provided the patient/patients' representatives necessary information to give informed consent prior to [redacted] on four (4) of four (4) Surgical Records reviewed (Patients #1, #2, #5 and #8).

Findings:

Record review for Patient #1 revealed that on [redacted]_

Response:

[redacted] follow-up [redacted]_

which dictate our standards of professional practice. Every patient is given written and oral information about every service and procedure as well as the opportunity to ask questions by a trained staff person or Social Worker. Once the staff person has ensured understanding, then informed consent is obtained. Physicians have always confirmed that consent has been obtained and they have always given the patient the opportunity to ask questions. Beginning June 16, 2014, we will ensure that the Physician/Surgeon documents that she/he reviewed the informed consent and answered any questions by adding a place on the visit record for such documentation. This change in documentation will be reflected in the Medical Protocols under [redacted].

All Physicians/Surgeons will be notified of this addition immediately. Beginning June 16, 2014, and for the next three months, PPNC will review all [redacted] abortion records to assure compliance with documentation of the physician's conversation with the patient relative to informed consent. Semiannual audits will be performed subsequently to ensure continued compliance.
**T2178 Continued From page 12**

53.1.14 the patient had a [redacted] procedure. The patient’s chart contained the patient’s signature dated 02/14 and the signatures of the witnesses whose signatures dated 02/14. The patient’s chart stated that the client got this information and understood it. The patient was able to ask any questions.

Record review for Patient #2 revealed that on 02/14 the patient had a [redacted] procedure. The patient’s chart documented the patient’s (and witness) signatures dated 02/14.

Record review for Patient #5 revealed that on 12/13 the patient had a [redacted] procedure. The patient’s chart documented the patient’s (and witness) signatures dated 12/13.

An interview with Staff #1 on the morning of 04/24/14 revealed that the Social Worker gives the Surgical and Anesthesia Consents to the patient during the pre-surgical testing visit. The Social Worker signs the Witness Section on the Consents. The Social Worker receives special training to perform this function.

Review of the facility’s policy titled [redacted] dated 2012, documented that clinicians performing abortions must ascertain that informed consent has been obtained before providing the abortion.

There was no documented evidence that the Physician / Surgeon discussed the surgical risks, benefits and alternatives with the patient prior to surgery as required.
**T2178** Continued From page 13

Similar findings were noted in the Medical Record for Patient #8.

**T2557** 755.4 (b) FREE-STANDING AMBULATORY SURGERY SERVICES.

Anesthesia services,

The operator shall ensure that:

(b) administration of anesthesia is in accordance with current standards of professional practice.

This Regulation is not met as evidenced by:

Based on record review and staff interview, it was determined that the facility failed to ensure the

recorded time the intraoperative vital signs were documented for four (4) of four (4)
records reviewed (Patients #1, #2, #3 and #8).

**Findings:**

Record review for Patient #1 revealed that on CNT 114 that the patient had a procedure. At ___ the surgery was started.

At ___ the CRNA's (Certified Registered Nurse Anesthesia) Note documented at ___

___ given. The dosage and route of the medications were not documented.

The Intraoperative Vital Signs Note documented blood pressure, ___ pulse, ___ respirations:

___ oxygen saturation rate, and level of

**T2577** Response:

The CRNA documented the ___ status of all ___ to patients. Using one of the examples given

will document the ___ with an expanded description as of June 16, 2014. The above example will now read,

In addition, ___ will have the CRNA time stamp the intra-operative vital signs beginning June 16, 2014. To ensure compliance, ___ will review all abortion records for the next three months. Semi-annual audits will be performed subsequently to assure continued compliance.
Record review for Patient #2 revealed that on 04/14 the patient had a [redacted] procedure. At the time the [redacted] procedure was started. The CRNA’s Note documented a [redacted] The medications were not documented.

Record review for Patient #3 revealed that on 04/13 the patient had a [redacted] procedure. At the time the procedure was started. The CRNA’s Note documented a [redacted] The medications were not documented.

The Intraoperative Vital Signs Note documented blood pressure [redacted], pulse [redacted], respiration [redacted], oxygen saturation [redacted], and [redacted] The above notations were not timed.

Review of the Medical Record for Patient #8 documented similar findings.
<table>
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<tr>
<th>Affected Facility Identification Number</th>
<th>Name of Facility or Supplier</th>
<th>Street Address</th>
<th>City, State, Zip Code</th>
<th>Prefix/Tag</th>
<th>Summary Statement of Deficiencies (each deficiency must be preceded by full regulatory or LEC identifying information)</th>
<th>Corrective Action</th>
<th>Complete Date</th>
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7556 (d) Free-Standing Ambulatory Surgery Services.

Patient admission and discharge:

The operator shall ensure that:

d) each patient is evaluated by a physician for proper anesthesia recovery, and discharged upon the written order of a physician.

This Regulation is not met as evidenced by:

Based on record review and staff interview, it was determined that the facility failed to ensure that the Physician ordered the discharge after assessing the patient's recovery from the anesthesia procedure in less than two (2) of two (2) weeks. Records reviewed (Patients #1 and #8).

Findings:

Record review for Patient #1 revealed that on April 4, 2014 at 3:00 pm, the anesthesia procedure was completed. At 3:00 pm, the Physician's Order documented to discharge the patient from the Recovery Room when able to controlled and able to follow up in weeks and no longer in need of pain medication. At 3:00 pm the nurse's note documented "discharged to Recovery Room." At 3:00 pm the patient was discharged.

Record review for Patient #8 revealed that on April 14, 2014 at 1:00 pm, the anesthesia procedure was completed. At 1:00 pm, the Physician's Order documented to discharge the patient from the Recovery Room when able to controlled and able to follow up in weeks and no longer in need of pain medication.

As of June 1, 2014, the protocol has been amended to include: "Each patient must be evaluated by the physician for proper anesthesia recovery and discharged upon the written order of the physician." Each physician providing surgical abortion services at the facility will receive notice of this change from the Medical Director on June 13, 2014 and will be required to discharge the patient from recovery when the patient has had proper anesthesia recovery. To ensure compliance, the facility will review all surgical abortion records for the next three months. Semi-annual audits will be performed subsequently to ensure continued compliance.
**New York State Department of Health**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
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<th>[x] PROVIDER/SUPPLIER/COLA IDENTIFICATION NUMBER:</th>
<th>[x] MULTIPLE CONSTRUCTION</th>
<th>(x) DATE SURVEY COMPLETED</th>
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**NAME OF PROVIDER OR SUPPLIER**

**STREET ADDRESS**

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**SUMMARY STATEMENT OF DEFICIENCIES**

**PROVIDER’S PLAN OF CORRECTION**

(Each deficiency must be preceded by full regulatory or CQC identifying information)
At the Physician was noted in a Procedure Room with another patient performing a... procedure. At the patient was observed in the Recovery Room.

It was noted that the Physician documented the procedure in the Procedure Room. The Physician did not order the discharge after assessing the patient's recovery from the procedure in the Recovery Room, prior to discharge as required.

T26597 756.5(g) ABORTION SERVICES. Nursing Services.

The operator shall ensure that:
1. only registered professional nurses function as circulating nurses in the operating room.

This Regulation... evidenced by:

Based on record review and staff interview, it was determined that the facility failed to ensure that a Circulating Nurse was in the Operating Room during the procedures for four (4) of four (4) records reviewed (Patients #1, #4, #6 and #7).

Findings:

Response: The staffing of abortion procedures is... nurse because:

756.5(c) should be read in conjunction with 756.5(e) which says "If abortions are performed in operating rooms, a registered professional nurse is in charge of the nursing services in the operating rooms". This does not require abortions to be performed in operating rooms, which is consistent with best practices for this type of procedure, which is typically conducted in a procedure room.

The staffing requirement of 756.5(c), which states "as a minimum, a licensed nurse is present in each treatment room when an abortion procedure is being performed". All abortion procedures are staffed with a licensed physician who performs the procedure, a Certified Registered Nurse Anesthetist (CRNA) who administers consciousness sedation and a Certified Assistant who is trained to work in the procedure room. The presence of the CRNA exceeds the minimum requirement of 756.5(c) that a licensed nurse be present in each treatment room.

Physicians, CRNAs and other trained staff working in procedure rooms are all trained to respond to emergencies if a complication should arise.
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<td><strong>SUMMARY STATEMENT OF DEFICIENCIES:</strong></td>
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<td><strong>(F) PROVIDER'S PLAN OF CORRECTION:</strong></td>
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<td><strong>(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCES TO THE APPROPRIATE DEFICIENCY):</strong></td>
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Office of Health Systems Management
STATE FORM

Americans United for Life
Record review for Patient #7 revealed that on 03/14 the patient had a [redacted] procedure. Staff #6 administered the [redacted] procedure. Staff #6 performed the [redacted] procedure.

Review of the [redacted] form dated 03/14 revealed Staff #7 was assigned to the PR.

Review of the Medical Record documented similar findings for Patient #4.

756.5 ABORTION SERVICES, Quality Assurance

In addition to the requirements set forth in section 751.8 of this Title, the operator shall ensure that there is a review of any abortion procedure complication with the use of those findings in the development and revision of policies and in consideration of renewing or granting staff privileges.

This Regulation is not met as evidenced by:

Based on record review and staff interview, it was determined that the Quality Assurance Program did not assess actual and potential problems concerning patient care and clinical performance. This was evident in three (3) of three (3) records identified in the facility's Incident Reports (Patients #2, #3 and #5).

Findings:

As a plan of correction for the next three months, the Senior VP for Health Services will ensure that each incident needing review by the Medical Director is reviewed and that his findings are used in the development and revision of policies and in consideration of renewing or granting staff privileges. Semi-annual audits will be performed subsequently to ensure continued compliance.
June 4, 2014

Re: Article 28 Survey

Dear [Name]

Enclosed is a Statement of Deficiencies relative to Chapter V, Title 10NYCRR. You must prepare a specific Plan of Correction including a timetable for implementation for each deficiency.

Your Plan of Correction must be submitted to this office by June 18, 2014. When submitting your Plan of Correction, please be certain to use the SOD/POC form and to sign and date the bottom of the first page.

Should you have any questions you may contact this office at [Contact Information]. Written correspondence should be sent to the New York State Department of Health.

Sincerely,

[Signature]
April 29, 2013

Re: Article 28 Diagnostic & Treatment Center Follow Up Survey
November 30, 2012

Dear [Name],

On May 12, 2011, staff in this office performed an Article 28 survey of the [Facility Name]. The purpose of the survey was to assess compliance with Title 10 New York Codes, Rules and Regulations (NYCRR) governing diagnostic & treatment center operations. The Statement of Deficiencies subsequently issued on June 2, 2011 cited several violations of regulations, including those addressing medical staff credentialing, quality assurance and infection control. [Facility Name] submitted a Plan of Correction (POC) and addendums which the Department of Health (DOH) deemed acceptable on November 29, 2011.

The purpose of this November 30, 2012 survey was to again assess compliance with Title 10 NYCRR, specifically following up the facility’s implementation of the previously acceptable POC. The Statement of Deficiencies (SOD) enclosed is based on the findings of the follow up survey. Many of the findings represent repeat deficiencies and demonstrate [Facility Name] did not implement several corrective actions in its prior POC. Please submit a new POC to this office at the following address within 10 business days of receipt of this letter: New York State Department of Health, [Address].

The POC should respond directly to the correction of each item identified, include a timetable for completion of the plan (see right side (X5) column on the SOD), and identify the person(s), by position, who are responsible for implementation and monitoring for continued compliance.

Please note that, where applicable, the POC must be implemented at all of your sites, not just the sites visited.

If you have any questions, please feel free to contact [Contact Person].

Sincerely,

[Signature]

Enclosure

cc: [Contact Person]
Y 000 INITIAL COMMENTS

PF1 [Redacted] OPERATING CERTIFICATE [Redacted]

NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A FOLLOW UP SURVEY CONDUCTED IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

Y4336 400.20 (a) (1) HIV INFECTION CONTROL

All facilities regulated under this article shall:
(1) implement and enforce a program for the prevention of circumstances which could result in an employee or patient/client becoming exposed to significant risk body substances which could put them at significant risk of HIV infection during the provision of services, as defined in section 63.1 and 63.9 of this Title.

This Regulation is not met as evidenced by:
Based on findings from observations, the [Redacted] does not maintain an environment that is free of circumstances which could result in an employee or patient/client becoming exposed to significant risk body substances.

Findings include:

Office of Health Systems Management

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [Redacted]

STATE FORM: [Redacted]
New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER

(X2) MULTIPLE CONSTRUCTION
A. BUILDING: __________________________
B. WING: __________________________

(X3) DATE SURVEY COMPLETED
11/30/2012

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

(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

Y4336  Continued From page 1

On 11/05/12, at the bathroom, unsecured, housed the used/filled sharps containers. The bathroom was used for storage until the containers could be picked up by the medical waste company, which comes. This finding was confirmed with the Vice President for Patient Services (VPPS) during the tour.

On 11/30/12, at the area where patients walked through. This was confirmed during the tour with LPN # 1.

T2019  751.2 (f) (7) ORGANIZATION AND ADMINISTRATION. Operator.

The responsibilities of the operator shall include but not be limited to: (f) ensuring that the following documents, as applicable, are retained on file in the administrative offices of the center: (7) the applications for admission to staff privileges of all current medical and dental staff, which shall include for each applicant: a statement of training and experience, all supporting documents, satisfactory evidence of conformity with requisite professional licensing laws and records of actions and recommendations of staff committees of the respective professional staff and of the governing authority.

This Regulation is not met as evidenced by:

Based on findings from document reviews and
T2019 Continued From page 2

Interview, all credentialing information required by this regulation is not maintained in the medical staff members' files.

Findings include:

-- Review of medical staff files for the Medical Director, Physician #1 and Nurse Practitioners (NPs) #1 & #2 revealed they did not contain the credentialing information obtained by [redacted], per contract arrangement. (This would be the credentialing information the Board reviews prior to the appointment and reappointment, and the granting and renewing of privileges for the medical staff.)

-- This finding was confirmed during interview with the Human Resource Supervisor (HRS) on 11/05/12.

This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11.

The operator never implemented the Plan of Correction (POC) accepted by the Department of Health (DOH) on 11/29/11.

T2022 751.2 (h) ORGANIZATION AND ADMINISTRATION. Operator.

The responsibilities of the operator shall include but not be limited to:

(h) the appointment of medical and dental staff, the assignment of their clinical privileges and reviews of such appointments at least every two years.

This Regulation is not met as evidenced by:
Based on findings from document reviews and interview, in 4 of 4 medical staff files reviewed for [redacted] medical staff members, evidence was...
T2022  Continued From page 3

lacking that the Board appointed all of the medical staff and approved assignments of their privileges. Also, the medical staff files lacked performance-related information required by facility policy and procedure (P&P) to be maintained in the files.

Findings include:

- Per review of the medical staff files for Physicians #1 and #2 (including the Medical Director), and NPs #1 and #2, each lacked documentation addressing the staff member’s appointment/reappointments and the clinical privileges assigned.

While the Board meeting minutes for 2011 through 2012 contained indications Physicians #1 & #2, and NP #1 were appointed or reappointed by the Board, they lacked documentation describing privileges granted. Additionally, there is no evidence NP #2 was appointed by the Board (despite date of hire listed as 02-12-12 in his/her medical staff file).
**T2022** Continued From page 4

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**T2022**

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"These findings were confirmed during interview with the HRS on 11/05/12.

This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. However, the POC accepted by the DOH on 11/29/11.

**T2068** 751.5 (a) (12) ORGANIZATION AND ADMINISTRATION.

Operating Policies and Procedures.
The operator shall ensure:
(a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice which include but are not limited to:
(12) the designation of a member of the center staff to be specifically assigned to implement policies and procedures for the coordination of the services of the center with the services of community health facilities and programs and community social agencies.

This Regulation is not met as evidenced by:

Based on findings from review of [redacted] manual, the facility lacked a written P&P addressing the designation of a specific staff member to coordinate services of the [redacted] with services of [redacted]. This was confirmed during interview with the VPPS on 11/05/12: he/she could only indicate there was a shared responsibility among professional staff for the coordination of services between the [redacted].

This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11.

T2070 75.15 (a) (14) ORGANIZATION AND ADMINISTRATION.

Operating Policies and Procedures.

The operator shall ensure:

(a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice which include but are not limited to:

(14) ensuring that emergency equipment and staff prepared to care for emergencies are provided in accordance with the services provided at the center, and equipment is maintained in working condition.
Continued From page 6

This Regulation is not met as evidenced by: Based on findings from observations and interviews, [redacted] did not store its emergency equipment where it would be immediately available for use at all times.

Findings include:

-- Per observations during tours on [redacted]

On 11/05/12, at the [redacted] the emergency box was located in exam room #1. It was/is not immediately available when a patient is being evaluated in the room, as was the case during the tour. This finding was acknowledged by [redacted] Manager [redacted] 1.

On 11/30/12, at the [redacted] the oxygen tank stored in the bottom of a cupboard was empty and not secured (as required by NFPA 99 per reference in 711.2(a)(20)), and the mask attached to it was exposed.

--During interview with LPN #1, he/she indicated they never use oxygen at the [redacted] and so don’t keep track of it.

-- However, the P&P titled [redacted] dated 01/2010, does include use of oxygen for emergencies.

T2097 751.6 (g) ORGANIZATION AND ADMINISTRATION. Personnel.

The operator shall ensure:

(g) the assignment of duties and functions to each employee that are commensurate with his/her licensure, registration and/or certification.
and experience and competence

This Regulation is not met as evidenced by: Based on findings from document reviews and interview, the facility's job descriptions for the Clinical Assistant/Clinical Receptionist (CA/CR), Licensed Practical Nurse (LPN), and Manager each contain duties which are not commensurate with the professional licensure and/or lack of licensure of the staff in these positions. Also, the facility failed to determine that LPN staff were competent in performing venipunctures prior to allowing them to perform this procedure.

Findings include

--- The CA/CR's job description describes duties that include restocking the exam, intake and medication rooms daily to assure efficient patient flow. Medications

The job description indicates this person is responsible for supervision/management of clinical operations at including supervision of RNs, LPNs, CAs, CRs, NPs, physician's assistants (PAs) and certified nurse midwives (CNMs), as well as medical residents and other clinical visitors. The this facility is a registered nurse (RN). The form that he/she completes for the NP, PA and CNM staff, documents assessments of the staffs' competencies for several clinical skills that are not in the scope of practice for an RN (e.g., applies tenaculum properly during IUC (intrauterine contraception) insertion; demonstrates judgement in reviewing the appropriateness of injectable Depo-Provera
for client; formulates appropriate diagnosis, treatment, HRT (hormone replacement therapy), as per protocol; etc.

The LPN Clinic Nurse job description indicates this person delivers patient care utilizing the nursing process to assess, plan, implement and evaluate patient outcome. The scope of patient care practice for LPNs in NYS does not include assessment activities.

- Per interview with LPN #1 at the time of hire on 11/29/12, he/she had been hired 8 months ago but never received any training or evaluation prior to performing the role. He/she did perform on the job training at prior place of employment.

The facility P&P titled "Nursing Staff Competency Program," dated 8/2012, contains the following statements:

"Staff with previous experience in this role still need to review and internalize Protocol and Infection Control Policies, take a written test, and demonstrate proficiency based on the procedure to a clinician. The proctor may use her discretion to determine the number of procedures (up to 3) needed to demonstrate proficiency...should be documented using the Training Checklist. No one will be considered trained without demonstrating proficiency to a clinician...all procedures will need to be observed and cosigned until the Module has been successfully completed and Statement of Competency signed."

Although the date of hire for LPN #1 was
T2097 Continued From page 9

10. 11. His/her personnel records contained a training checklist dated 11/12, with the signed Statement of Competency dated 1/12.

Although, the date of hire for LPN #2 was 12/2012, his/her personnel records contained a training checklist dated 11/12, with the signed Statement of Competency dated 12/12.

It was confirmed through interview with the VPPS on 12/12 that both LPNs performed at the facility prior to completion of the competency verification process.

T2114 751.7 (d) ORGANIZATION AND ADMINISTRATION.

Medical record system.
The operator shall:
(d) ensure that the medical record for each patient contains and centralizes all pertinent information which identifies the patient, justifies the treatment and documents the results of such treatment.

This Regulation is not met as evidenced by: Based on document reviews, 4 of 5 medical records (MR) reviewed for abortion patients lacked complete documentation, i.e., the form in the MRs lacked one or more of the following:

* date of service,
* ultrasound date and findings,
* vital signs,
**T2114** Continued From page 10

* signature of a nurse or clinical assistant, and/or
* follow up visit date.

**T2140** 751.8 ORGANIZATION AND ADMINISTRATION.

Quality assurance program.

This Regulation is not met as evidenced by:
Based on findings from document reviews and interview, the quality assurance (QA) program at [redacted] does not include all pertinent services in its QA activities, does not follow up on all significant issues identified, and does not address the requirements at 751.8(d)(1)-(4) and (f) under this regulation. Additionally, issues that are reviewed during meetings of the facility's [redacted] committee are not clearly described in its meeting minutes.

Findings include:
<table>
<thead>
<tr>
<th>Statement of Deficiencies and Plan of Correction</th>
<th>Provider/Supplier/Clinical Identification Number</th>
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<tr>
<td>(X1) PROVIDER/ SUPPLIER/ CLINICAL</td>
<td>A Building: ____________</td>
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<td>IDENTIFICATION NUMBER</td>
<td>B Wing: ____________</td>
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<tr>
<td>(X2) MULTIPLE CONSTRUCTION</td>
<td>DATE SURVEY COMPLETED: 11/30/2012</td>
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<thead>
<tr>
<th>Name of Provider or Supplier</th>
<th>STREET ADDRESS, CITY, STATE, ZIP CODE</th>
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<th>ID</th>
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Office of Health Systems Management
STATE FORM
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T2140, Continued From page 12

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Office of Health Systems Management
STATE FORM
T2440  Continued From page 13

T2440

T2440  752-1.5 (e) CENTER SERVICES.

Pharmaceutical Provisions.

The operator shall ensure that:

(e) pharmaceutical services are provided in accordance with current standards of professional practice.

This Regulation is not met as evidenced by:
Based on findings from observation, document reviews, and interview, the facility was not providing pharmaceutical services in accordance with current standards of professional practice. Specifically, opened, unlabeled pharmaceuticals and other substances were observed in examination rooms at [redacted] toured. This problem was previously identified by the facility but not addressed.

Findings include:

- Per observations during tours of [redacted]
T2240, Continued From page 14

* On 11/05/12, opened and undated multidose bottles of injectable Lidocaine were observed available for patient use in the examination rooms.

* On 11/28/12, 2 opened and undated multidose bottles of injectable Lidocaine were observed available for patient use in the exam room at the

* On 11/30/12, an opened multidose bottle of injectable Lidocaine dated 10/27/12, greater than 30 days earlier, was observed available for patient use in room #1 at the

These findings were confirmed with #1 during the tours of the, with #2 during the tour of the, and with the Office Manager during the tour at the

For example:
Also, despite the continued findings illustrating staff were not practicing appropriate infection control measures specific to the handling of medications and other patient care supplies subject to expiration dates, the minutes of the [redacted] committee meetings from 01/12 through 07/12 lack indication the committee addressed this problem.

This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. PPNCNY never implemented the POC accepted by the DOH on 11/29/11.

Also see the findings in Tag T2040 which describe lapses in QA activities relative to pharmacy services.

U7045 702.4 INFECTION CONTROL AND REPORTING.

Infection control and reporting.

This Regulation is not met as evidenced by: Based on findings from observations, at [redacted] areas used for the following functions were not compliant with generally accepted infection control (IC) practices: blood draw/laboratory, dirty utility,
U7045  Continued From page 16

clean utility, and medication storage and preparation. Also, although the facility has established an [committee and performs audits, the audits are not performed at [and they lack assessment of staff's injection and handwashing practices. Additionally, not all lapses in [practices identified at the facility are addressed by the [committee.

Findings include:

-- Per observations during a tour of the [room on 11/26/12, the dirty [was a combination [and [It contained the autoclave where dirty equipment is brought in to be washed and autoclaved. The room was also being used for [  

-- During a tour of the [room on 11/29/12, LPN #1 indicated that urine samples are brought into the [room in order to enter patient data into the computer.

-- Per observations during a tour of the [room on 11/29/12, equipment was observed in the [room. It was confirmed with RN #1 that [activities were being performed in the [room.
Also see finding in Tag Y4336 regarding the facility's failure to store sharps containers in a manner that would avoid inadvertent staff or patient contacts with potentially infectious contents.

This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. The POC never implemented the POC accepted by the DOH on 11/29/11.
I Attachment

EHR Documentation Audit-Annual Visit.docx

Good morning,

Please find attached the corrected audit (revisions are highlighted in yellow).
Please contact me should you have any questions or concerns.

Thanks,

From: [Redacted]
Sent: Thursday, January 02, 2014 3:31 PM
To: [Redacted]
Cc: [Redacted]
Subject: POC

Attached is the "Annual Visit EHR Documentation Audit" which needs to be corrected.

I have written in pencil the changes/additions that need to be made. Next to the Advance Directive completed, HCP given to patient 18 and older....you need to add or parent of a child or married. That is consistent with NYCRR Title 10 Regulation 400.21. Please make the corrections and send the corrections to this email address not BML one. Once I receive it, you will have acceptable POCs and a letter will be sent.

I am out of the office until 1/10/14. If you have any questions please contact me on 1/10/14. [Redacted] will not be able to assist you.

Thanks - Hope your holidays were nice.
Thank you.

RESPONSES MUST BE SENT TO THIS E-MAIL ADDRESS ONLY.

12/05/2013 04:30:37 PM

Good afternoon [Name]
Please find attached...

December 5 DOH submission

12/05/2013 04:30 PM

to: [Name] Hospital BML

Good afternoon [Name]
Please find attached our documents for the December 5th submission.
Just one zip file this time!
The document index outlines materials submitted.
<table>
<thead>
<tr>
<th>NAME</th>
<th>Terms</th>
<th>Board Position, Committees</th>
<th>Home Address/County</th>
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**KEY:** EC=Executive Committee BDC=Board Development Committee FC=Finance Committee FUNCOM = Fund Development Committee FPA=FPA Board Member BPC=By-Laws & Policies Committee DIV=Diversity Committee SPC= Strategic Planning Committee PPANY=Planned Parenthood Advocates of NY Board Member LOA=Leave of Absence

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Abbreviated Executive Summary

Earlier this year, [omitted] was notified by [omitted] that their [omitted] in [omitted] was scheduled to close and that [omitted] services would no longer be available in [omitted] County. With the consent of the board [omitted], began the process of exploring establishment of [omitted] services in [omitted] County to avoid a hiatus in services for the community. [omitted] submitted an application to [omitted] and a letter of intent to the NYS Department of Health to add [omitted] County to our service area and was approved. In [omitted] 2013 we were notified by the DOH’s [omitted] that our request to set up services was reviewed and that [omitted] funding in the amount of [omitted] would be allocated to our existing [omitted] DOH grant for [omitted] County. These funds are contingent upon gaining approval of this certificate of need to establish a service site and are included in the DOH’s [omitted] budget which begins on [omitted] 2014. The [omitted] County Public Health Department has also indicated their interest in granting us a contract to carry out [omitted] services in the county in 2014. This contract is contingent upon our ability to open a service site currently serves 10 counties in [omitted] New York – [omitted] are located in [omitted]. Adding [omitted] County is in keeping with our mission to serve [omitted] New York.

Once approval was received, following discussion with the County Public Health Department, an earnest and exhaustive search for professional space in the [omitted] area was begun. An inspection of the clinical space currently used by [omitted] in [omitted] was performed. There were several deficiencies noted that would have to be corrected before approval could be obtained by the NYSDOH. [omitted] Deemed cost prohibitive, [omitted] began to look for alternative sites. [omitted] will end all of its services in [omitted] in [omitted] 2013.

- No existing free standing clinical/professional space was found for sale or lease in [omitted].
- Meetings were held with [omitted] County Public Health. The public health department could not identify any available Article 28 health center space in either [omitted].
- A visit to [omitted] was done to view their [omitted]. The size of the [omitted] is limited and has full usage. They have no available space in their [omitted].
Discussions with [Redacted] revealed they had no space in their building available nor in the building the clinic currently sits in. It was suggested by [Redacted] to inquire about leasing clinical space at [Redacted] in [Redacted] which occupied the space several years ago while awaiting another lease for lease. Two space options were inspected. The first option is to lease already
leased, however a portion of this space is currently leased by [Redacted] and [Redacted] for specific days of the week, The clinic consists of [Redacted]. The second option is [Redacted] would like to develop this under-utilized space and would work with [Redacted] to design and construct clinical space for sole use. This would not be immediately available and would take up to a year to do the renovations to specification, seek approvals and open the clinic. Based on the needs of the community and a potential hiatus in essential services which cannot be obtained elsewhere in [Redacted] consulted with County Public Health officials and the New York State Department of Health Article 28 team about leasing space in the nearby parking temporarily and begin working with [Redacted] to develop the space at the time. Several meetings were held with the Article 28 team to develop the plan for potential use of the facility. Approval and support was obtained from all.

In this Certificate of Need [Redacted] is seeking approval to add a new clinic site by leasing existing space from [Redacted]. This allows for optimal use of existing space and offers easy access to services that [Redacted] offers, including laboratory, ultrasound, mammography, x-ray and referral services, immediately. The [Redacted] is centrally located in [Redacted] has ample parking and offers patients an accessible, modern, new site to receive services. The site proposes to offer a full range of family, primary care, specialty care to the site would be staffed by an advanced practice clinician and a clinic assistant with
supervision provided by the VP for patient services in [redacted] and the [redacted] Medical Director.

Once the decision was made to pursue leasing space in the [redacted] that [redacted] reached out for guidance from NYSDOH agencies including:

- Bureau of Project Management
- Bureau of Maternal and Child Health
- Office of Health Systems Management

We reviewed the information provided to us by officials from these agencies and returned to [redacted] to discuss their recommendations. [redacted] was able to accommodate the recommendations given to [redacted] during our conference calls with NYSDOH officials. [redacted] obtained the services of an Article 28 Architectural firm to assess the site and produce certified architectural drawings demonstrating that [redacted] will have a sufficient amount of space to the [redacted] area to be leased and certify that all specifications and regulations have been met. (See Schedule 6) During [redacted] hours of operation, signage will clearly indicate the entrance for [redacted] will have a [redacted] for patients [redacted] staff access to a [redacted] There will be no co-mingling of any other provider’s patients. A [redacted] will be placed in the [redacted] to prevent co-mingling of patients. [redacted] plans to lease space [redacted] [redacted] With the use of electronic health records and secure internet connection, no co-mingling of patient charts will occur nor any HIPPA violations. [redacted] clinical staff will bring [redacted] lap tops for use during the clinical hours. [redacted] plans to utilize separate phone lines while in the clinical area by bringing and using [redacted] phones. A secured and locked closet will be available for storage of supplies [redacted] will need during clinic hours and which no one else will have access to.

The Operating Certificate (Certificate No [redacted] Effective date [redacted] 03) issued by the NYSDOH Office of Health Systems Management for [redacted] contains approved services which include Primary Care O/P indicating that this wing of the hospital is an Article 28 space.
Great!

From: [Redacted] On Behalf Of [Redacted]
Sent: Tuesday, September 10, 2013 2:38 PM
To: [Redacted]
Subject: Re: Article 28 site survey response cover letter

Received!

RESPONSES MUST BE SENT TO THIS E-MAIL ADDRESS ONLY.

[Redacted]

Good afternoon [Redacted],

Please find attached the cover letter for the Article 28 Site Survey Response.

Good afternoon [Redacted],

Please find attached the cover letter for the Article 28 Site Survey Response. Due to the size of the zip folders containing the supporting documents for the response to the SOD, we'll be sending an additional two emails. I'll be sending them with a receipt request. Please contact me should you have any questions. Thanks kindly,
second zip file

To:

09/10/2013 02:19 PM
Show Details

History: This message has been replied to.

Thanks....
Article 28 site survey response cover letter

to:

09/10/2013 02:16 PM
Cc:

History: This message has been replied to.

Good afternoon,

Please find attached the cover letter for the Article 28 Site Survey Response. Due to the size of the zip folders containing the supporting documents for the response to the SOD, we'll be sending an additional two emails. I'll be sending them with a receipt request. Please contact me should you have any questions.

Thanks kindly.
September 9, 2013

Re: Article 28 Diagnostic and Treatment Center Follow Up Survey
November 30, 2012

Dear [Name],

In response to your letter of August 27, 2013 we have made revisions to the plan of correction related to the subject follow-up survey. You will find in the attached file the following changes in policies and procedures and forms and documents requested.

Tag 2068:
1. The [Redacted] policy and procedure has been revised
2. The Lead Clinician Job Description has been revised

Tag 2070:
1. The [Redacted] has been revised
2. Form: [Redacted]
3. Form: [Redacted]

Tag 2097:
1. Annual Skills form revised
2. CA/CR duties revised
Tag 2114:
1. Description of number of abortion charts to be audited per site.
2. Clinic Work Plan revised

Tag 2240:
1. Response to deficiencies noted in cover letter
2. Revised pharmaceutical policy and procedure that addresses the statement of deficiency surrounding medication distribution
3. Description of audit process for infection control practices
4. Documentation that Pharmacy Consultant is being consulted
5. Credentials of Infection Control Specialist
6. Updated Pharmacy Consultant attestation

Tag U 7045:
1. APIC Infection Control Specialist’s review and recommendations

Please contact me should you have questions regarding any of the documents we have submitted.
Good afternoon,

Please find attached the cover letter for the Article 28 Site Survey Response. Due to the size of the zip folders containing the supporting documents for the response to the SOD, we'll be sending an additional two emails. I'll be sending them with a receipt request. Please contact me should you have any questions.

Thanks kindly,
Policy Statement: In order for [redacted] to provide the best services to our patients, [redacted] acknowledges that a specific staff person must be assigned to coordinate the services of all affiliate centers with the services of [redacted] and [redacted].

Procedure:

- The Lead Clinician will be tasked with the coordination of services. This task will be reflected in the Lead Clinician’s Job Description.
- The Lead Clinician will be responsible for updating each center’s referral book annually and as needed.
- The Lead Clinician will be responsible for new staff training on the coordination of services.
- Patient referrals will be evaluated monthly by the clinician who has initiated the referral. This will be noted in the referral log book by the ordering provider’s initial and date. All NP’s and PA’s employed by [redacted] have been approved to initiate referrals in accordance with [redacted] Standards and Guidelines. Lead clinician will evaluate referrals monthly by phone, site visits and/or staff meetings.
- Recommendations for out of affiliate screening are at the discretion of the patient.
- Any patient who is determined to require emergent care will be referred to the ER immediately and followed up within 24 hours with a phone call, 72 hours if it is a Friday.
- Clinicians will consult with either the lead clinician or medical director on any patient they deem acute and requiring immediate referral.
Employee: ______________________  Job Title: ______________________

Review for: ____ End of Probation  ____ Yearly Evaluation

The following section will be completed by lead clinician evaluator:

<table>
<thead>
<tr>
<th>A. CLINICAL SKILLS</th>
<th>Fully Competent</th>
<th>Needs Improvement</th>
<th>Not Trained</th>
</tr>
</thead>
</table>

1. General
- Refers to current edition of affiliate protocols as needed.
- Introduction of self to client:
- Explains NP/PA/CNM role as requested/appropriate.
- Briefly orient client to procedures.
- History taking:
- Reviews history thoroughly.
- Elicits additional information in a concise manner.
- Demonstrates organization in interviewing technique.
- Completes thorough chart review.
- Documents concisely with appropriate descriptive terminology.
- Prepares forms and other written materials in a legible and well-organized manner.

2. Specimen Collection
- Use of proper technique to collect Pap test:
- Adequately samples endocervix with cytobrush/swab, as appropriate.
- Samples entire squamo-columnar junction.
- Applies cells evenly to slide and fixes within 5 seconds (for slide based Pap).
- Rinses liquid-based spatula and brush correctly and within 30 seconds to prevent fixation.
- Use of good technique for wet mount preparation:
- Properly handles specimen.
- Accurately identifies organisms.
- Clinician makes sure specimens are labeled correctly.

3. Sexually Transmitted Infections (STI)
- Review of sexual history, including STI risk assessment:
- Offers appropriate screening.
- Uses appropriate criteria for diagnosis.
- Use of clean technique:
- Washes hands before and after each patient.
- Avoids contamination of "clean" hand throughout entire exam.
- Avoids contamination of "clean" inanimate objects during entire exam.
- Avoids contamination of clean parts of lab specimens (outside tubes, caps, pap, etc.).
- Uses the "inside out" technique for removing glove.

4. Specific Birth Control Methods
- Use of barrier methods:
  - Direct observation  □ Chart review  □ Diaphragm
- Chooses appropriate size.
- Provides instructions.

2010
Confidential Property of

[Signature]
## A. CLINICAL SKILLS

<table>
<thead>
<tr>
<th>Category</th>
<th>Fully Competent</th>
<th>Needs Improvement</th>
<th>Not Trained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier Methods Requests return demonstration when appropriate.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>IUC Insertion:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>□ Direct observation □ Chart review □ Paraguard □ Mirena</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Obtains appropriate informed consent documentation.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does bimanual prior to insertion.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Explains procedure.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Uses good technique in cleansing cervix.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Applies tenaculum properly.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Sounds uterus using good technique.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Uses measurement obtained by sounding measure expected depth of uterine activity.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Inserts IUC using manufacturer's instructions.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Use of Implants:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>□ Direct observation □ Chart review □ Implanon □ Norplant (removal only)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Obtains appropriate informed consent documentation.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Prior to insertion and removal, skin is prepped properly.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Maintains sterile field during insertion.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Follows manufacturer's instructions for removal.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>For Norplant, in removal, incision is &lt;5 mm.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Implant(s) is removed without undue trauma.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Clinician demonstrates competency in educating clients about removal.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Injection of DMPA:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Clinician demonstrates judgment in reviewing appropriateness of DMPA for client.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Completes necessary chart review prior to DMPA administration (LMP, PT, etc.)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. GYN Services □ Direct observation □ Chart review</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Takes appropriate history &amp; education, as per protocol.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Performs complete exam and identifies normal and abnormal findings.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Formulates appropriate diagnoses, treatment, HRT, as per protocol.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Provision of Services Related to Medication Abortion</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Generation of provision of services related to pregnancy termination:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Sizes uterus accurately via ultrasound.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Provides thorough post-AB assessment</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Is able to discern normal versus abnormal post-AB findings</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Obtains appropriate informed consent documentation as needed.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Explains procedures as performed</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Completes exam systematically and efficiently.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Accurately identifies normal and abnormal findings</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Identification of assessment/clinical impression</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Identifies risk factors for BCM chosen</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Accurately interprets lab findings.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Accurately interprets physical findings.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Synthesizes information from history and physical to form assessment/clinical impression.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Medical Abortion-con't</td>
<td>Fully Competent</td>
<td>Needs Improvement</td>
<td>Not Trained</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------</td>
<td>------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Is able to discern normal versus abnormal findings.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**A. CLINICAL SKILLS**

<table>
<thead>
<tr>
<th>7. Men's Health Services</th>
<th>Direct observation</th>
<th>Chart review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognizes/assesses deviations from normal.</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Appropriately diagnoses and manages conditions in male patients, per protocol.</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. Management/Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performs/orders lab tests per protocol with respect for individual needs and economy.</td>
</tr>
<tr>
<td>Accurately provides BCM with respect for individual needs.</td>
</tr>
<tr>
<td>Accurately provides medications based on assessment.</td>
</tr>
<tr>
<td>Refers/recommends as appropriate per protocol and based on individual needs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Proficiency Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test type:</td>
</tr>
<tr>
<td>Slice test/other</td>
</tr>
<tr>
<td>Hcg</td>
</tr>
<tr>
<td>Rapid HIV</td>
</tr>
<tr>
<td>Other:</td>
</tr>
</tbody>
</table>

---

**Part II ATTACH THE FOLLOWING:**

☐ [Blank space] if indicated

---

"Americans United for Life"
Major Strengths: ________________________________

______________________________

______________________________

______________________________

Major Weaknesses: ________________________________

______________________________

______________________________

______________________________

**Developmental Plan:** Wherever performance is identified as unsatisfactory or marginal define a plan to bring performance level to acceptable standards. Do the same for identified major weakness.

______________________________

______________________________

______________________________

<table>
<thead>
<tr>
<th>Overall Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>( ) Unsatisfactory</td>
</tr>
<tr>
<td>( ) Satisfactory</td>
</tr>
<tr>
<td>( ) Off Probation</td>
</tr>
</tbody>
</table>

Evaluation Completed by: ______________________ Date: __________

Employee Signature: ______________________ Date: __________

VPPS Signature: ______________________ Date: __________

Medical Director Signature: ______________________ Date: __________
CLINIC ASSISTANT/

JOB TITLE: CLINICAL RECEPTIONIST | STATUS: Non-exempt

REPORTING TO: Manager

POSITION SUMMARY: Provides education and patient care under the supervision of a RN/Provider related to family planning, pregnancy and options counseling, reproductive health, abortion, colposcopy, LEEP and sexually transmitted infections for males and females.

ESSENTIAL DUTIES:

Customer Service Skills
1. Answers telephones in timely professional manner.
2. Greets patients and visitors in a positive friendly manner.
3. Routes calls appropriately.
4. Receives patient calls, writes accurate messages and puts charts up for clinic staff to review and return patient call.
5. Accurately registers and schedules patients in practice management system.
6. Collaborates with clinical and non-clinical team members to provide excellent internal and external customer service and satisfaction.
7. Responds to patient calls in a timely manner while providing accurate information.
8. Adhere to affiliate goals and policies on professionalism, wait time and on the phone, and the system for addressing client complaints.

Clinic Support
1. Understands and demonstrates compliance with policies and procedures related to providing patients with birth control supplies.
2. Accurately documents in the medical records.
3. Retrieves medical records for internal and external quality management audits or as required.
4. Prepares patient charts for all visits.
5. Transfers and receives patient medical records according to policy and procedure.
6. Demonstrates accuracy in receiving, documenting and filing of patient laboratory results in accordance with procedures.
7. Responsible for patient reminder calls, reschedules cancellations and no show patient visits.
8. Works as a part of a team to maximize productivity standards of 4 patients per hour.
9. Reviews monthly financial and patient visit reports.

**Financial Support**
1. Provides accurate information costs of the visit and collect payment at time of the visit. Assist patients with billing issues.
2. Accurately collects and enters insurance information in the practice management system, and obtain copies of all insurance cards at each visit. Obtains consents for billing.
3. Completes patient financial interviews, assigns correct fee categories, and facilitates enrollment in the [program name].
4. Conducts audits to ensure documentation accurately reflects reimbursement and patient pay class assigned is correct.
5. Accurately registers patient in the Practice Management system, assesses demographics and contact status.
6. Participate in health center/affiliate efforts to achieve established revenue cycle goals.

**Patient Care**
1. Under the supervision of licensed clinical staff, provides non judgemental education and care related to family planning, reproductive health and STI's for males and females.
2. Interviews patients on entrance to the [program name] prior to the exam.
3. Review patient plan of care and reinforces teaching documented by the clinician.
4. Provides interventions as ordered by clinician, and documents in patient medical record according to [DOH, NAF] standards and guidelines.
5. Initiates and completes follow up as ordered by clinical staff regarding abnormal labs and test results according to follow up protocols.
6. Provides support, under the supervision of a RN/LPN/Provider, to patients receiving colposcopy,LEEP and Abortion services according to surgical standards and protocols.
7. Assures [program name] has adequate supplies in stock to deliver patient care. Completes inventory on a monthly basis and completes request for supplies to be ordered. Prepares [program name] exam rooms for [number] visits.
8. Restocks exam, intake and medication rooms daily to assure efficient patient flow under the general supervision of licensed staff.
9. Performs various medical lab functions, collecting blood and urine specimens, pregnancy testing, blood pressure, hemoglobin, weight and height while using aseptic technique and universal precautions.
10. Provides HIV counseling and testing under clinical staff guidance.
11. Accurately documents in the medical record. Writes legibly.
12. Complies with HIPAA rules and regulations.
13. Other duties as assigned.

REQUIRED SKILLS AND ABILITIES:

1. Ability to organize, prioritize and manage multiple tasks and data with accuracy, attention to detail, flexibility while maintaining confidentiality.
2. Excellent interpersonal skills with ability work cooperatively with internal and external customers of diverse backgrounds.
3. Excellent verbal, written and computer skills.
4. Commitment to core values of teamwork, compassion, confidentiality and quality care.
5. Acceptance and understanding of Personnel Policies.
6. Ability to travel to other centers as needed
7. Current certification in BLS/CPR.
8. [Redacted]
9. Willingness to work flexible hours.
10. Assists in training of new employees.

QUALIFICATIONS:

1. High School diploma or GED required.
2. Family Planning/GYN office experience preferred.
3. Direct patient care experience and computerized medical office operations experience preferred.

PHYSICAL DEMANDS/WORKING CONDITIONS

1. Lift/carry 10 lbs. or less frequently, and up to 50 lbs occasionally
2. Bend/squat/kneel frequently
3. Twist/turn constantly
4. Climb stairs frequently
5. Type/keyboard constantly

________________________
Employee’s Printed Name

________________________
[Signature]
**Emergency Medical Box Contents**

- All emergency boxes are immediately accessible and not behind locked doors during clinical sessions.
- A licensed professional is responsible for maintaining the emergency box medications and supplies.
- Monthly checks of the emergency box are performed by licensed personnel and documented with signature. A record is kept of monthly checks.
- A tamper-proof lock is kept on all emergency boxes. It is removed at the time of monthly checks and emergencies, and is then replaced.
- Contact your local state agency for other regulations regarding maintenance of the emergency box (i.e., some states require the emergency box to have a second lock that is fastened when medical services are not being provided).
- The Emergency Medical Box will be audited/inspected monthly and after each procedure if contents used. The staff will document the audit/inspection on the monthly checklist/After Use Inspection Audit.

**Representative List of Emergency Contents for Centers Providing Surgical Services**

*Note: Misoprostol is used for post-abortion hemorrhage, especially for clinics that do not stock Hemabate. In addition, some affiliates prefer to stock the following medication in their emergency box (must be refrigerated): Carprofen tromethamine (Hemabate) 250mcg/ml.

- Classification: Prostaglandin
- Action: Stimulates myometrium contraction of the uterus
- Uses: Unlabeled use to reduce blood loss secondary to uterine atony
- Dosage: 250mcg IM; may repeat every 10-15 minutes if no response not to exceed 12mg
- Side Effects: Fever, flushing, chills, cough, headache
Executive Summary
Introduction

[Company Name] is a company specializing in infection prevention and control solutions. Utilizing the expertise of our industry-leading consultants, works in various healthcare settings to prevent and control healthcare-acquired infections (HAIs). With access to leading resources and world-renowned experts in infection control, no other consulting firm offers the level of knowledge and expertise. [Company Name] is a wholly owned subsidiary of the [Parent Company Name]. For over 16 years, [Company Name] has been the leader in striving to end healthcare-associated infections for over 16 years. [Company Name] was created to assist in these efforts by bringing expertise directly to clients to offer customized solutions.

[Consulting Firm Name], contracted by [Company Name], to conduct a comprehensive assessment of the facility, with the goal of specifically addressing the New York State Department of Health (NYSDOH) Statement of Deficiencies (SOD) associated with breaches in infection control standards for ambulatory care centers. The assessment was to include both a review of relevant data and documents as well as a comprehensive onsite evaluation to identify problem areas and provide recommendations for addressing the infection control SOD's facility specific and/or system-wide. As of March 26, 2013, [Company Name] had not received the official NYSDOH SOD report.

The assessment was performed by an certified [Infection Control Professional] with over 15 years of infection control and prevention experience. [Infection Control Professionals] all meet the following criteria:

- Must be CIC®, Certified in Infection Control through the Certified Board of Infection Control and Epidemiology, Inc.
- 15 years + experience within infection control and prevention
- Hold a RN or higher degree from an accredited institution

Background and methodology

[Background and methodology text]
• Processing of specimens not compliant: cannot bring specimen from dirty utility room to clean utility room to be entered into computer.

A review of these anticipated NYSDOH infection control deficiencies identified the following categories requiring assessment:

• Quality controls for sterilization processing of instruments.

• Handling and disposal of used needles/syringes.

• Internal handling/transportation of laboratory specimens.

• Outdated multi-dose medication vials.

• Blood drawing activities in medication preparation areas.

• Availability of personal protective equipment (PPE).

• Appropriate use of refrigerator thermometers.
In preparation for the on-site facility visit, multiple documents were reviewed to assess organizational system-wide infection control policies/procedures for each of the identified categories identified and consistent with published standards and federal/state infection control regulations. Documents reviewed included:

- NY state regulations addressing infection control practices.
- Recognized publications for infection control standards of practices.
- Policies on competency processes to ensure employee knowledge of the infection control practices related to the anticipated deficiencies and with the identified infection control breaches.

Recommendations

1. Designated areas for autoclaves

   A. The [blank] autoclave should be relocated from the [blank] office to a dedicated sterilization only work area. Until facility renovations can establish a dedicated work area, the autoclave can be temporarily relocated to the instrument cleaning and laboratory processing room. The autoclave must be physically separated from the designated instrument cleaning area. Signage must be readily visible to designate the physical separation. No instrument cleaning or laboratory processing tasks are to be performed during instrument sterilization activities. At the completion of each instrument sterilization cycle, processed items must be removed from the room and stored in clean area.

   B. The [blank] infection control manuals need to include guidelines designating and identifying the most appropriate work area for autoclaves.

2. Post-sterilization instrument verification

   A. Use of tags to identify instruments awaiting sterilization process are not necessary and should be discontinued in all facilities. Wrapped packs and unwrapped trays should only be placed in the autoclave just prior to initiating the sterilization cycle. A change in either the process heat sensitive tape/integrated tab or chemical indicator strip are one of the tools to be used in verifying if a set of wrapped and/or unwrapped instruments has completed the sterilization cycle.
B. The tool used to record sterilization parameters at the completion of each processed load should be referenced to verify a completed sterilization cycle. Records need to be maintained per state and local requirements.

C. System-wide, all staff, who are directly responsible for the sterilization of instruments, should be retrained and competency assessed for how instruments are verified after completion of the sterilization cycle.

D. System-wide, all staff, who access or use wrapped or packaged instruments, should be reeducated and competency measured on how to identify sterilized from unsterilized instruments, both commercial and in-house processed products.

E. The CDC/OSHA infection control manuals should update the guidelines for assessment and documentation of sterilization parameters, both mechanical/physical and internal chemical process indicators (tape/chemical indicators), for each autoclave type.

3. Monitoring and implementation of instrument sterilization processing quality controls

A. A system-wide sterilization quality control program needs to be developed and implemented as outlined in the CDC’s Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, pp 91-92.

B. Consider replacing the Ritter® table top autoclave at the facility, as well as at the other facilities, with newer and a more efficient models.

C. Review and confirm what type of autoclaves are used in each facility and ensure they are operated per manufacturers’ operating instructions and sterilization parameters are consistent with the infection control manual guidelines.

D. Discontinue the practice of sealing instrument peel pouches with heat sensitive process autoclave tape. Peel pouches should be a self-sealing product, or if not available then heat sealed.

E. It is required that a process indicator (i.e. heat sensitive tape or tab integrated into peel pouch) be affixed to the outside and a multi-variable chemical indicator strip be placed inside of each peel pouch and wrapped pack.

F. A multi-variable chemical indicator strip classified as class 4 or 5, should be considered for peel pouches and wrapped packs. Refer to American National Standard (ANSI)/AAMI Sterilization of Healthcare Products—Chemical Indicators—Guidance for Selection, Use and Interpretation of Results, 2008.
G. The single-variable class 3 chemical indicator strip currently used, which is intended to respond to only one parameter of the sterilization process, is appropriate for placement in each unwrapped instrument tray being processed.

H. A label on each peel pouch, wrapped pack and unwrapped autoclave load is required to include; a load number, processing date and operators initials. The same information is required to be documented either manually or if available, or an autoclave digital printout.

I. At the completion of each sterilization load, the mechanical/physical (time, temperature and psi) and results of the external process and internal chemical indicators needs to be recorded. Records need to be maintained per state and local requirements.

J. Staff directly responsible for the processing of instruments for sterilization should receive comprehensive training on standards of practice for monitoring and ensuring sterilization of instruments. Ensure staff understand manufacturers’ operating instructions. Update competency of staff to evaluate understanding of changes aimed at ensuring quality controls for all sterilization processes.

K. Staff responsible for instrument sterilization may benefit in updating their instrument processing knowledge by shadowing central sterile supply personnel at an area hospital.

L. A written corporate policy needs to be established for sterilizing instruments from non-affiliated facilities. The policy should establish if and how processing, sterilizing and transporting instruments by facilities not associated with will be implemented.

M. Update the infection control policies and instructions for removing each autoclave load, which should include assessment and documentation of the load meeting sterilization cycle parameters for mechanical/physical and all process/chemical indicators (tape/chemical indicators).

N. Update all sterilization policies to be in compliance with the Centers for Medicare & Medicaid Services (CMS) CFR 42.416.51 regulations recently published in the CDC’s Guidelines on Infection Control in Ambulatory Surgical Centers 2011 and Infection Control in Ambulatory Surgical Centers Checklist 2011.

O. Review of sterilization monitoring results should be incorporated into the quality assurance program. Sterilization monitoring results from all facilities should be reviewed quarterly by the infection control committee and semi-annually by corporate quality assurance administrator(s).
4. Storage and rotation of sterile supplies

A. A par-stock system should be established for vaginal speculums in client examination rooms. Only the number of vaginal speculums needed each day should be in the examination warming drawer. At the end of the day, the examination table drawer should be wiped with a PDI™ disposable disinfectant cloth and drawer restocked from the in-room cart drawer. Newly reprocessed vaginal speculums should be placed in either the cart drawer or a covered plastic storage container in each examination room.

5. Separation of instrument cleaning (dirty), sterilization, laboratory processing and medication preparation work areas

A. There must be a locked door separating instrument cleaning areas from sterile processing work stations. Doors are necessary is important to prevent entry of unauthorized non-facility personal into facility work processing areas. needs a locked door to the instrument cleaning work area and another door separating the from the hallway entrance into the work stations. needs a door separating the work area from the patient examination area.

B. There must be separate and designated work areas for instrument cleaning and sterilization activities, laboratory processing and medication preparation tasks. Laboratory specimens cannot be brought into the sterile processing work area for any reason. Laboratory processing cannot be performed in medication preparation and storage areas. Where structural barriers (walls, doors, etc.) cannot be constructed to physically segregate these work areas, signage must be clearly posted identifying the work area and entry by authorized personnel only.

C. Blood drawing procedures should be performed in patient examination rooms.

6. Outdated multi-dose medication vials

A. needs to develop comprehensive client specific safe injection practices program that incorporates; standards for appropriate use of single and multi-use needles, syringes, and multi-dose medication vials lacks a comprehensive set of written standards addressing safe injection practices to protect patients from exposure to infectious agents. Policies need to be in compliance with the CMS CFR 42.416.51 regulations recently published in the CDC's Guide to Infection Prevention for Outpatient Settings: Minimum Expectations of Care and Checklist, 201
B. Staff responsible for the administration and/or handling of single and multi-dose medication vials should receive comprehensive training on safe injection practices to prevent and protect patient exposure to infectious agents. Update staff competency to evaluate understanding safe injection practices aimed at protecting patients from exposure to infectious agents per CMS CFR 42.416.51 regulations.

7. Handling and disposal of used needles and syringes as RMW

A. Staff responsibilities should be established for changing and replacing sharps containers.

B. Floor-style in-use sharps collection canisters used in patient examination rooms need to be secured and locked.

C. Provide address labels for each facility that can be affixed to the in-use sharps containers.

D. Develop a written policy and guidelines for transporting RMW to other facilities for licensed vendor pickup. Guidelines should be consistent with NYSDOH PHL and RMW part 70 regulations.

E. There needs to be education and competency standards developed and provided to individual(s) responsible for transporting RMW to off-site facilities.

F. Staff needs reeducation on differentiating regulated from non-RMW. Request the RMW vendor to provide education to staff on types of regulated and non-RMW and requirements for disposal (facility/vendor) and transporting between facilities. Solicit the licensed vendor to support and conduct RMW education for all facilities.

8. Availability of PPEs

A. Staff responsibility should be established for assessing and par-stocking client examination rooms.

B. PPEs should be visibly and readily accessible, but not overstocked in each room or work area where there is potential/anticipated employee exposure to blood and blood fluids.
JOB TITLE: Lead Clinician       STATUS: Non Exempt

REPORTING TO: VP of Patient Services

POSITION SUMMARY: The Lead Clinician assists in the oversight of the medical programs and quality management of patient care provided by [______]. The Lead Clinician assists in the compliance with [______], Medical Standards and Guidelines, state and local regulations, community standards, and [______] policies. The Lead Clinician provides guidance and mentors clinic staff on medical practice issues, policies and procedures. The Lead Clinician is the coordinator of services between [______] and community health facilities, programs and community agencies. In addition, the Lead Clinician provides direct medical care to family planning and abortion patients.

ESSENTIAL DUTIES:
1. Provides agency orientation, teaching and coaching for Nurse Practitioners and Physicians Assistants.
2. Provides clinical leadership by teaching, coaching and consultation on clinical management issues for all clinical staff.
3. Assists with the facilitation of the semi-annual provider meetings.
4. Conducts annual evaluations for all midlevel clinicians with input from VPPS and Medical director
5. Contributes to the overall effectiveness of the agency by adhering to established agency policies and practices.
6. Addresses provider training needs as directed by the Medical Director and VP of Patient Services.
7. Provides ongoing technical assistance and in-service training for licensed and unlicensed staff on an intermittent basis in collaboration with the Medical Director, VP of Patient Services and Regional Managers.
8. Maintains productivity expectations and compliance of agency standards
9. Conducts on site Peer Review, chart and referral audits at all clinics as required.
10. Performs medical screening procedures as appropriate for [______] clients.
11. Performs reproductive health assessments for female and male clients.
12. Refers clients with abnormal conditions found on examination to the Medical Director and/or other physicians or medical facilities as needed per health center guidelines and/or client needs.

13. Serves as the agency coordinator for the referral and coordination of social services for clients requiring these services. The Lead Clinician who will travel across the affiliate will work with all affiliate staff to assure that referrals are made. The Lead Clinician will liaise with the VP of Community Services at provider meetings to obtain updates on referral services.

14. Performs, orders and interprets routine laboratory tests.

15. Responsible for follow up of abnormal lab tests.

16. Performs medical referrals as indicated and appropriate follow up.

17. Participates in in-service training and community education as assigned.


19. Serves as a resource person for patient or medical information calls.

20. Documents findings and referrals as required.

21. Adhere to affiliate policies on professionalism, wait time and on the phone, and the system for addressing client complaints.

22. Participates in health center efforts to achieve established goals for productivity.

23. Participates in health center/affiliate efforts to achieve established revenue cycle goals.

24. Works independently to maintain up to date knowledge in the health care field via attending seminars and workshops and reading relevant material.

25. Assists in product evaluation.

26. Performs other duties as assigned.

OTHER

1. Communicates clearly and promotes a customer-focused vision and mission for self and staff.

2. Acts proactively, anticipates problems and initiatives new and better ways of care delivery.

REQUIRED SKILLS AND ABILITIES:

1. Ability to organize, prioritize and manage multiple tasks and data with accuracy, attention to detail, flexibility and confidentiality.

2. Excellent interpersonal skills with ability to work cooperatively with internal and external customers.

3. Excellent business English, Microsoft Word, database, and Excel skills.

4. Commitment to core values of teamwork, compassion, patient confidentiality and quality care.

5. Acceptance and understanding of Personnel Policies.

6. Ability to travel.

7. Embraces the concept of team building and values internal and external customer satisfaction.
QUALIFICATIONS:

1. Valid NP/PA license in New York State.
2. Current DEA license.
3. 5 years of demonstrated experience in reproductive health management is required with at least a year of prior experience with [blank] or other [blank] providers.
4. Proven leadership skills, which build teamwork, enlist cooperation and confidence. Capacity to mentor and build leadership skills in others.
5. Professional positive attitude with proved ability to contribute effectively to highly functioning work teams.

PHYSICAL DEMANDS/WORKING CONDITIONS

1. Lift/carry 10 lbs. or less frequently, and up to 50 lbs occasionally
2. Bend/squat/kneel frequently
3. Twist/twist constantly
4. Climb stairs frequently
5. Type/keyboard constantly

__________________________  ________________________
Employee’s Printed Name    Date

__________________________  ________________________
Employee’s Signature        Date

__________________________  ________________________
Supervisor’s Signature      Date
Please complete this form monthly. Initial and date in the appropriate box.
In keeping with the guidelines set forth by [redacted] and all state/local laws and regulations, the following policies will be implemented by [redacted].

[redacted] contracts with a qualified pharmacist(s) to assist in the development of policies and procedures for providing medications and biologics. Moreover, the pharmacist consult will provide an annual and as needed review of practices, policies and procedures. (refer to [redacted]).

**Procurement:**
The Medical Director only approves drugs approved by the FDA and only those from FDA certified manufacturers to be prescribed, dispensed and distributed at [redacted].

Drugs which may be prescribed by affiliate clinicians for patients to obtain at outside pharmacies include:

- All contraceptives listed in [redacted].
- All medications listed in [redacted].
- All drugs recommended for treatment of Sexually Transmitted Diseases in the current Summary of CDC Treatment Guidelines.
- [redacted] mg [redacted] as directed, [redacted] mg [redacted], as directed, or equivalent short acting anxiolytic, as a pre-medication for any procedure/exam at [redacted] including abortion.

**Storage:**
The drug storage areas of pharmaceuticals at [redacted] are secured at all times. The following staff at [redacted] may have access to the drug storage area for reason of stocking, inventory management, dispensing or distributing medication: Physicians, Physician Assistants, Nurse Practitioners, RN’s, LPN’s. Clinical Assistants, Clinical Receptionists and the Inventory Manager may restock under the supervision of licensed staff.

Medications may only be dispensed by licensed staff. Licensed staff may select the medication prescribed by the provider/physician and complete the label requirements as outlined below under **Labeling**

**Distribution of Medications by Non-Licensed Staff**
Non-licensed staff may only distribute medication that has been previously dispensed by a provider/physician and placed in a central location for distribution; the non-licensed staff may select the medication labeled with a particular patient’s name and provide and/or distribute it to the patient named. In addition, non-licensed staff may also select a medication that has been prescribed by provider/physician and prepare the medication with the proper label, but prior to the medication distribution, it must be checked by the provider for accuracy and approval for distribution.
Pharmaceuticals meant for internal use must be separated from those for external use. Clear and visible labeling is required.

Pharmaceuticals in all storage areas must be arranged so that the oldest stock is used first. On a monthly basis designated licensed staff will inspect the drug storage area for expiration dates. All expired medications will be disposed of according to policy. (See Disposal of Pharmaceuticals Policy)

Pharmaceuticals requiring refrigeration will require continuous temperature control monitoring for quality control. All refrigerators will be equipped with a data storage thermometer. Temperatures will be monitored and documented twice daily on the temperature log. When centers are not opened, temperatures will be retrieved from the thermometer’s data storage and the minimum and maximum temperatures will be recorded on log. Should temperatures fall below or above recommended guidelines, pharmaceuticals will be disposed of according to the proper disposal procedures (see policy on disposal of pharmaceuticals)

Repackaging: [BLANK] does not repackage medications
Repackaging must be done in accordance with state/local laws/regulations.

A log must be maintained to document the supervisor (by signature), the person doing the repackaging (by signature) and the identification of the bulk drug being repackaged. Logs must be archived for two years. 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 that will link that manufacturer and drug lot with the repackaged units

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 facility
- Name of the drug
- 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 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 (for example,
control # 012104, where 01=month, 21=day of repackaging, and 04=fourth item repackaged that day)

**Labeling Prepackaged Prescriptions for Patients:**
All prepackaged units are received at [Blank] with a permanent label affixed directly to the package with at least the following information:
- Name and address of the affiliate
- Name and strength of the drug
- Manufacturer and distributor if different from the manufacturer
- Standard directions for use including: frequency and route of administration

The label must also include the following information, which may be added by hand at the time of dispensing by the provider/physician, RN, LPN
- Name of provider prescribing medication
- Date of prescription at the time of dispensing
- Name of patient

Auxiliary labels particular to each individual drug will be used and placed on package as needed.

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.

**Controlled Substances:**
[Blank] does not carry, maintain or dispense controlled substances.

**Other:**
It is the policy of [Blank] that multi-dose injectable medication vials must be labeled with the date that they are opened and then be disposed of 28 days later, except for Tubersols which are disposed of 30 days after being opened and vaccines which are disposed of by their expiration date. (For proper disposal see [Blank] "Disposal of Pharmaceuticals Policy and Procedure")

All patients who receive medications from [Blank] receive written or verbal instructions including the name, purpose, and appropriate administration technique for each drug. Patient package inserts must be provided for IUC's, hormonal contraceptives, and other estrogenic and progestational substances. Patient drug information is provided on all other drugs dispensed. All patient education is documented in the medical record.
Management of Pharmaceutical Product Irregularities

Pharmaceutical product irregularities may be detected in the form of defects in drug or device packaging, tablet disoloration, or dose sequencing. Such problems may be the result of a defective manufacturing or packaging processes, failure of the pharmaceutical company’s product inspection mechanism, or tampering with the product at any point between the product’s packaging and its use by the patient. Because these products may be dangerous to the patient and because other units may be defective, prompt action is necessary to deal with these events.

When an irregularity of a pharmaceutical product is suspected, the following must be done:

- The package of medication in question must be held in a secure place at the affiliate, as later transfer to the manufacturer or the FDA may be necessary. There must be no attempt to manipulate or otherwise alter the package, as it may constitute evidence in a criminal suit or other action.
- Remaining stock of medication with the same lot number must be identified, put aside, and not dispensed to patients until the problem has been resolved.
- Medical affairs must be notified immediately by telephone for evaluation of the situation and provision of further instructions. will not take any additional steps (such as notification of the pharmaceutical company, FDA, other patients who may have been exposed to the product, and the media) until it receives guidance from:

Drug and Device Recalls

The FDA initiates drug recalls of drugs or devices that are found to be in violation of federal law. The recalls are classified according to the potential adverse impact of the volatile drug or device upon the health exposed individuals.

Definitions:
Class I recalls are situations in which there is a reasonable probability that the use of or exposure to a volatile product will cause serious adverse health consequences or death.

Class II recalls are situations in which use of or exposure to the volatile product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
Class III recalls are situations in which use of or exposure to a volatile product is not likely to cause adverse health consequences.

Procedures:

Class I Recalls

- Purchase logs must be evaluated for a period of not less than two years prior to the date of the recall.
- All volatile product must be quarantined. Product must not be provided to any patient until it is verified that stock does not contain involved lot numbers.
- Any of the volatile product found in stock must be removed from the inventory unless otherwise indicated in the recall information.
- If it is determined that none of the volatile lot(s) have been received at [___], then the only further action required is to verify that none of the involved lots are shipped to the health center during the next two months.
- If it is determined that product from the volatile lot(s) has been provided to patients within the past two years, the following actions must be taken:
  - Daily computerized tracking logs and/or medical records must be reviewed to determine which patients received product from the volatile lot(s).
  - An attempt must be made to contact identified patients by telephone.
    - If it is determined that the patient received the product from the volatile lot(s), or if the lot cannot be determined, the patient must be instructed to discontinue the medication and bring it back to the [___] immediately for replacement with an uninvolved lot of the same medication, if available. If a non-involved lot cannot be obtained for the patient, the patient must be changed to an alternate medication.
    - If is determined that the patient received the named medication, but not from the involved lot(s), she or he should be reassured that continuation with their prescribed regimen is safe.
  - If an identified patient cannot be contacted by telephone, a letter must sent to her/him, explaining the nature of the recall and requesting that the [___] be contacted.
  - If a patient experiences a significant medical problem resulting from the use of the volatile product, [___] Medical Affairs and ARMS must be informed.

Class II Recalls

- Purchase logs for the past year must be checked to determine if any of the volatile lots have been received.
- Any volatile product found in stock must be removed from inventory and prepared for return to the supplier.
• If it is determined that the product from the volatile lot(s) has been provided to patients within the last six months, the following actions must be taken:
  ○ Daily computerized logs and/or medical records must be reviewed to determine which patients received product from the volatile lot(s).
  ○ An attempt must be made to contact identified patients by telephone.
    ▪ If it is determined that the patient received product from the volatile lot(s), the nature of the recall must be explained and the patient must be requested to return any outstanding supply of the volatile product to the clinic.
    ▪ If it is determined that the patient received the named medication, but not from the involved lot(s), she or he should be reassured that continuation with their prescribed regimen is safe.
  ○ If an identified patient cannot be contacted by telephone, a letter must be sent to her/him, explaining the nature of the recall and requesting the return of any outstanding volatile product.
  ○ If a patient experiences a significant medical problem resulting from the use of the volatile product, Medical Affairs and must be informed.

Class III Recalls:
• No product lot listed in a Class III recall may be provided to a patient.
• The volatile substance must be removed from inventory and returned to the supplier.
Statement of Compliance

I have reviewed the attached Pharmacy Services policies and procedures and find them to be in compliance with all New York State Department of Health, SED Board of Pharmacy and regulatory requirements.

[Signature]
Pharmacist Consultant

[Date]
9-9-13
PHARMACIST CONSULTANT CONTRACT

This agreement is entered into between ___________________________ (hereinafter referred to as Employer) located at ___________________________ and ___________________________ (hereinafter referred to as Pharmacist) located at ___________________________.

Employer will schedule an onsite consultation with New York State Licensed Pharmacist annually and other consultants as needed.

The Pharmacist will provide overview and assistance regarding:
- Maintenance and development of policies related to medications and biologics
- Annual review of pharmaceutical practices, policies and procedures
- Disposal of expired or deteriorated medications and biologics
- Storage, dating, labeling and monitoring of expiration dates
- Documentation of written prescriptions
- Medical record review
- Physical plant inspection

Following the onsite audit, the Pharmacist will provide a written report of findings within 30 days to the VP of Patient Services.

The Pharmacist will provide a copy of their current NYS License.

The Pharmacist will be paid $50.00/HR for services conducted. Travel reimbursement will be $0.52 per mile.

The Pharmacist will sign confidentiality and HIPAA agreements. (See Attachments A and B)

Signed ___________________________  Signed ___________________________
President and CEO                     Pharmacist

Date 9.4.2013                          Date  9-9-13
<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
</table>
| Albuterol Inhaler  
Expires: | |
| Atropine 0.4mg/ml  
Expires: | |
| Compazine 5mg/ml  
Expires: | |
| Diphenhydramine (Benadryl) 50mg cap  
Expires: | |
| Diphenhydramine (Benadryl) IM 50mg/ml  
Expires: | |
| Epinephrine 1:1000 (1mg/ml)  
Expires: | |
| Mephine 0.2mg/ml (Refrigerator)  
Expires: | |
| Toradol 30mg/ml  
Expires: | |
| Solu-Medrol 125mg/2ml  
Expires: | |
| Misoprostol 200mg #4 (Pburgh only) | |
| Alcohol Prep Pads | |
| AA Batteries | |
| Band-Aids | |
| Bulb Syringe | |
| 4x4 Sterile Gauze Pads | |
| Exam Gloves (non-latex) | |
| 3ml Syringes with 21g Needles | |
| TB Syringes | |
| Angiocaths – 18, 20 | |
| IV Tubing | |
| IV Solution – LR or NS 500ml  
Expires: | |
| 23 3/4G Butterfly | |
| Tourniquet | |
| 3-0 Chromic | |
| Sterile Suture Set | |
| Airways | |
| Ambu Bag & Non-Rebreather Mask | |
| Nasal Cannula | |
| CPR Shield | |
| Foley Catheter | |
| Stethoscope | |
| Oxygen Tank with liter meter >¾ full | |

*After completion, please give a copy of this form to your Manager and the RQM*
Emergency Cart/Equipment Inspection: After Use

Date __________

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Expiration</th>
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</thead>
<tbody>
<tr>
<td>Albuterol Inhaler</td>
<td></td>
<td></td>
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<tr>
<td>Atropine 0.4mg/ml</td>
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<td></td>
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<tr>
<td>Compazine 5mg/ml</td>
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<tr>
<td>Diphenhydramine (Bendryl) PO 50mg caps</td>
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<tr>
<td>Diphenhydramine (Benadryl) IM 50mg/ml</td>
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</tr>
<tr>
<td>Epinephrine 1:1000 (1mg/ml)</td>
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<tr>
<td>Solu-Medrol 125mg/2ml</td>
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<tr>
<td>Alcohol Prep Pads</td>
<td></td>
<td></td>
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<tr>
<td>Adhesive Tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4x4 Sterile Gauze</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3ml Syringes with 22g Needles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB Syringes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 3/4g Butterfly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Solutions – LR or NS 500ml</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Tubing</td>
<td></td>
<td></td>
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<tr>
<td>Tourniquet</td>
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<tr>
<td>Angiocaths –18 or 20</td>
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<tr>
<td>Airways</td>
<td></td>
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<tr>
<td>Ambu Bag</td>
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<tr>
<td>Nasal Cannula</td>
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<tr>
<td>CPR Shield</td>
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<tr>
<td>Non-Rebreather Mask</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen Tank with liter meter &gt;¾ full</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*After completion, please give a copy of this form to your Manager and the RQM.

Note: All emergency medications must be ordered 2 months prior to expiration date.
Plan of Correction

<table>
<thead>
<tr>
<th>Monitoring and Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Lead clinician will be in monthly contact with all providers to review referrals. Contact will be during visits or monthly staff meeting or by phone. Refer revised Coordination of Services policy</td>
</tr>
<tr>
<td>● Refer to lead clinician job description #13</td>
</tr>
</tbody>
</table>

Completion Date

| 9/4/2013 |
| 9/4/2013 |
Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: T2068
Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

<table>
<thead>
<tr>
<th>Plan of Correction</th>
<th>Implementation/Monitoring</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Annual skills form reflects lead clinician is evaluating mid level providers</td>
<td>• Annual skills form revised to reflect change</td>
<td>• 9/13</td>
</tr>
<tr>
<td>• CA/CR may be assigned duties of restocking meds under the general supervision of licensed staff</td>
<td>• In compliance</td>
<td>• 9/13</td>
</tr>
</tbody>
</table>
Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

<table>
<thead>
<tr>
<th>ID PREFIX TAG: t2097</th>
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<tbody>
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</table>
Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013  
Regarding Article 28 Diagnostic and Treatment Survey of 2012  

**ID PREFIX TAG: T2070**

<table>
<thead>
<tr>
<th>Plan of Correction</th>
<th>Implementation and Monitoring</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspections of emergency equipment will be done, at a minimum, monthly and after each use of the equipment and will be documented appropriately.</td>
<td>Emergency response equipment will be inspected, at a minimum, monthly and after each use. Completed inspections will be documented on the Monthly Cleaning/Maintenance and Safety Checklist and After Use Inspection. (see attached) Managers will be made immediately aware of malfunctioning or outdated equipment in need of replacement/repair. Checklists will be reviewed by managers monthly.</td>
<td>This plan will be implemented immediately.</td>
</tr>
</tbody>
</table>

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**DOH POC: 13**
Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: T2070
RE: Article 28 D&TC Survey-completed September 10, 2013

Dear [Name],

This letter follows the completion of an Article 28 survey at your facility. The purpose of this survey was to determine compliance with Article 28 requirements for a D&TC facility.

Enclosed are the Article 28 Statement of Deficiencies listing areas of non-compliance. You must prepare and submit a Plan of Correction to address the deficiencies. The Plan of Correction must be explicit and include the date of correction, a description of the corrective action, and a prospective plan to ensure continuing compliance in the future.

NOTE: Please ensure that the Plan of Correction submitted include the “provider/supplier representative’s signature (X6)” near the bottom of page 1, as well as the “completion date (X5)” entries in the far right column of each page.

The Article 28 Plan of Correction must be submitted to our office located at [Address] no later than October 15, 2013.

If you have any questions concerning this letter, please call [Phone Number].

Sincerely,

[Signature]

cc: [Name]

(Enclosure)
<table>
<thead>
<tr>
<th>T000</th>
<th>INITIAL COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFI #&lt;redacted&gt;</td>
<td>OPERATING CERTIFICATE #&lt;redacted&gt;</td>
</tr>
</tbody>
</table>

NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A SURVEY CONDUCTED IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

<table>
<thead>
<tr>
<th>T2022</th>
<th>761.2 (h) ORGANIZATION AND ADMINISTRATION. Operator.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The responsibilities of the operator shall include but not be limited to:</td>
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<tr>
<td></td>
<td>(h) the appointment of medical and dental staff, the assignment of their clinical privileges and reviews of such appointments at least every two years.</td>
</tr>
</tbody>
</table>

This Regulation is not met as evidenced by: Based on document review and interview, the operator does not ensure the appointment of medical staff along with the assignment of clinical privileges and reviews of such appointments every two years, as evidenced for 2 of 2 staff. (Staff #1 and 2)

Findings include:

Review on 9/9/13 of facility bylaws revealed the
<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2022</td>
<td>Continued From page 1 operator will review appointments and reassign clinical privileges at least</td>
<td>T2022</td>
<td></td>
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<tr>
<td></td>
<td>Review on 9/9/13 of credential files for Physician Staff #1 and 2 revealed no evidence of the appointment/reappointment process, including requests for renewal of clinical privileges and reappointment, curricula vitae, current CME completion and peer review. These findings were verified with Staff #1 on 9/9/13.</td>
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<tr>
<td>T2074</td>
<td>751.5 (c) ORGANIZATION AND ADMINISTRATION. Operating Policies and Procedures. The operator shall ensure: (c) that the center's policies and procedures are reviewed at least annually and revised as necessary. This Regulation is not met as evidenced by: Based on document review and interview, the operator does not ensure that all facility policies and procedures are reviewed at least annually and revised as necessary. Findings include: Review on 9/10/13 of the policy and procedure manual for the lab and infection control program revealed no evidence of review or revision at any time. This finding was verified with Staff #1 on 9/10/13.</td>
<td>T2074</td>
<td></td>
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</tbody>
</table>
The operator shall ensure:

(k) that each employee, as applicable, receives on-the-job training necessary to perform his/her duties.

This Regulation is not met as evidenced by:
Based on document review, personnel file review and interview, the facility does not ensure that each employee who performs duties at the facility has proof of completion of on-the-job training to perform such duties. (Staff #3)

Findings include:

Review on 9/9/13 of job description revealed the staff member who will complete training provided by the physician. In addition, 50 cases are to be reviewed by the physician for accuracy and proficiency before the staff member would be considered proficient in the task of performing duties.

Review on 9/9/13 of the personnel file for Registered Nurse Staff #3, revealed no evidence of completion of job orientation/training to perform duties.

These findings were verified with Staff #1 on 9/10/13.

751.7 (c) ORGANIZATION AND ADMINISTRATION.

Medical record system.
The operator shall:
(c) ensure that the medical record supervisor...
<table>
<thead>
<tr>
<th>ID</th>
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<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tbody>
<tr>
<td>T2113</td>
<td>Continued From page 3</td>
<td>receives consultation from a qualified medical record practitioner when such supervisor is not a qualified medical record practitioner.</td>
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<td>This Regulation is not met as evidenced by:</td>
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<td></td>
<td>Based on interview, the</td>
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<td>Findings include:</td>
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<td></td>
<td>Interview on 9/10/13 with Staff #1 revealed</td>
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<tr>
<td>T2145</td>
<td>751.8 (d) (1) ORGANIZATION AND ADMINISTRATION.</td>
<td>Quality assurance program.</td>
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<td>(d) The quality assurance process shall define methods for the identification and selection of clinical and administrative problems to be reviewed. The process shall include but not be limited to:</td>
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<td>(1) the establishment of review criteria developed in accordance with current standards of professional practice for monitoring and assessing patient care and clinical performance.</td>
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<td>This Regulation is not met as evidenced by:</td>
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<tr>
<td>T2237</td>
<td>752-1.5 (b) CENTER SERVICES. Pharmaceutical Provisions.</td>
<td>T2237</td>
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<td>The operator shall ensure that:</td>
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<td>(b) when medications and biologicals are handled by personnel in the center in the absence of a pharmacy, there shall be</td>
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<td>consultation from a qualified pharmacist to assist in the development of policies and procedures for providing medications</td>
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<td>and biologicals.</td>
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<td>This Regulation is not met as evidenced by:</td>
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<td>U7036</td>
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<td>Continued From page 5</td>
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<td>U7036</td>
<td></td>
<td>702.3 (a) FIRE AND SAFETY.</td>
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<td>Buildings and equipment shall be maintained and operated so as to prevent fire and other hazards to personal safety.</td>
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<td>Findings include:</td>
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<td>- near the electrical breaker-box: scrap wood and chunks of concrete;</td>
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<td>- by the hot water tank: broken down cardboard boxes, numerous fluorescent light bulbs and water hoses;</td>
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<td>- near the generator: a large pile of scrap wood.</td>
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<td>This finding was verified with Staff #1 on 9/9/13.</td>
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<td>U7037</td>
<td></td>
<td>702.3 (b) FIRE AND SAFETY.</td>
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<td>The facility shall comply with the pertinent provisions of NFPA 101, Life Safety Code.</td>
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<td>Further details concerning this referenced material are contained in section 711.2(a) of this Title.</td>
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<td>This Regulation is not met as evidenced by:</td>
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<td></td>
<td>Based on observation and interview, the facility does not conduct 30-day fire extinguisher inspections, as evidenced for 4 of 4 fire extinguishers.</td>
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</tbody>
</table>
Findings include:

During facility tour on 9/9/13, it was observed that the fire extinguishers in the following locations were not inspected at least every 30 days:
- [Blank]
- [Blank]
- [Blank]

During interview on 9/9/13, Executive Director Staff #13 revealed that the required 30-day inspections for fire extinguishers were not conducted.

This finding was verified with Staff #1 on 9/10/13.

Based on document review, observation and interview, the facility does not maintain the fire alarm system, as evidenced that there is not evidence that all smoke detectors in the facility are inspected and tested.

Findings include:

Review on 9/9/13 of the fire alarm inspection and testing report dated 8/13, completed by [Blank] revealed the report documented that there were 7 smoke detectors in the facility. However, during facility tour on 9/9/13, 16 smoke detectors were identified in the facility.

This finding was verified with Staff #1 on 9/10/13.

Based on observation and interview, the facility does not maintain 4 of 5 battery-powered
**U7037** Continued From page 7

emergency lighting units in proper working order.

Findings Include:

During facility tour on 9/9/13, the "test" button was activated on the battery-powered emergency lights in the following areas, but the lights did not illuminate:

This finding was verified with Staff #1 on 9/10/13.
New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION
A. BUILDING:
B. WING:

(X3) DATE SURVEY COMPLETED
09/10/2013

NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

(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

T 000

INITIAL COMMENTS

PFI #:
OPERATING CERTIFICATE #:

NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A SURVEY CONDUCTED IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

/ T2022

751.2 (h) ORGANIZATION AND ADMINISTRATION. Operator.

The responsibilities of the operator shall include but not be limited to:
(h) the appointment of medical and dental staff, the assignment of their clinical privileges and reviews of such appointments at least every two years.

This Regulation is not met as evidenced by:
Based on document review and interview, the operator does not ensure the appointment of medical staff along with the assignment of clinical privileges and reviews of such appointments every two years, as evidenced for 2 of 2 staff. (Staff #1 and 2)

Findings include:

Review on 9/9/13 of facility bylaws revealed the

RECEIVED

OCT 15 2013

NYS HEALTH DEPARTMENT

Americans United for Life
**Summary Statement of Deficiencies**

- **T2022** Continued From page 1
  - Operator will review appointments and reassign clinical privileges
  - Review on 9/9/13 of credential files for Physician Staff #1 and 2 revealed no evidence of the appointment/reappointment process, including requests for renewal of clinical privileges and reappointment, curricula vitae, current CME completion and peer review.
  - These findings were verified with Staff #1 on 9/9/13.

- **T2074** 751.5 (c) ORGANIZATION AND ADMINISTRATION.
  - Operating Policies and Procedures.
  - The operator shall ensure:
    - (c) that the center's policies and procedures are reviewed at least annually and revised as necessary.
  - This Regulation is not met as evidenced by:
    - Based on document review and interview, the operator does not ensure that all facility policies and procedures are reviewed at least annually and revised as necessary.
  - Findings Include:
    - Review on 9/10/13 of the policy and procedure manual for the program revealed no evidence of review or revision at any time.
    - This finding was verified with Staff #1 on 9/10/13.

**Provider's Plan of Correction**

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<th>ID PRELIFIX</th>
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<tbody>
<tr>
<td>T2022</td>
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<td>T2074</td>
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<tr>
<td>T2101</td>
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The operator shall ensure:

(k) that each employee, as applicable, receives on-the-job training necessary to perform his/her duties.

This Regulation is not met as evidenced by:
Based on document review, personnel file review and interview, the facility does not ensure that an employee who performs
at the facility has proof of completion of on-the-job training to perform such duties. (Staff #3)

Findings include:

Review on 9/9/13 of the job description revealed a staff member who performs
will complete training provided by the physician. In addition, 50 cases are to be reviewed by the physician for accuracy and
proficiency before the staff person would be considered proficient in the task of performing

Review on 9/9/13 of personnel file for Registered Nurse Staff #3, who performs
for the facility, revealed no evidence of completion of job orientation/training to perform

These findings were verified with Staff #1 on 9/10/13.
T2113 Continued From page 3

receives consultation from a qualified medical record practitioner when such supervisor is not a qualified medical record practitioner.

This Regulation is not met as evidenced by:

Based on interview, the operator does not ensure

Findings include:

Interview on 9/10/13 with with Staff #1 revealed

T2145 751.8 (d) (1) ORGANIZATION AND ADMINISTRATION.

Quality assurance program.

(d) The quality assurance process shall define methods for the identification and selection of clinical and administrative problems to be reviewed. The process shall include but not be limited to:

(1) the establishment of review criteria developed in accordance with current standards of professional practice for monitoring and assessing patient care and clinical performance.

This Regulation is not met as evidenced by:
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<td>752-1.5 (b) CENTER SERVICES,</td>
<td>T2237</td>
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<tr>
<td></td>
<td>Pharmaceutical Provisions.</td>
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The operator shall ensure that:

(b) when medications and biologicals are handled by personnel in the center in the absence of a pharmacy, there shall be consultation from a qualified pharmacist to assist in the development of policies and procedures for providing medications and biologicals.

This Regulation is not met as evidenced by:

Findings include:

Review on 9/9/13 of facility contracts and staff meeting minutes revealed no evidence of employment of a consulting qualified pharmacist.

Interview on 9/9/13 with Staff #1 revealed that a
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<td>Continued From page 5</td>
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<td>U7036</td>
<td>702.3 (b) FIRE AND SAFETY.</td>
<td>09/10/2013</td>
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Buildings and equipment shall be maintained and operated so as to prevent fire and other hazards to personal safety.

This Regulation is not met as evidenced by:
Based on observation and interview, the facility does not maintain all clinic space free of hazards.

Findings include:

During facility tour on 9/9/13, there were three areas in the [redacted] that contained construction waste:
- near the electrical breaker-box: scrap wood and chunks of concrete;
- by the hot water tank: broken down cardboard boxes, numerous fluorescent light bulbs and water hoses;
- near the generator: a large pile of scrap wood.

This finding was verified with Staff #1 on 9/9/13.

The facility shall comply with the pertinent provisions of NFPA 101, Life Safety Code. Further details concerning this referenced material are contained in section 711.2(a) of this Title.

This Regulation is not met as evidenced by:
Based on observation and interview, the facility does not conduct 30-day fire extinguisher inspections, as evidenced for 4 of 4 fire extinguishers.
Findings include:

During facility tour on 9/9/13, it was observed that the fire extinguishers in the following locations were not inspected at least every 30 days:

During interview on 9/9/13, Executive Director Staff #13 revealed that the required 30-day inspections for fire extinguishers were not conducted.

This finding was verified with Staff #1 on 9/10/13.

Based on document review, observation and interview, the facility does not maintain the fire alarm system, as evidenced that there is not evidence that all smoke detectors in the facility are inspected and tested.

Findings include:

Review on 9/9/13 of the fire alarm inspection and testing report dated 3/13, completed by revealed the report documented that there were 7 smoke detectors in the facility. However, during facility tour on 9/9/13, 16 smoke detectors were identified in the facility.

This finding was verified with Staff #1 on 9/10/13.

Based on observation and interview, the facility does not maintain 4 of 5 battery-powered...
### New York State Department of Health

**Statement of Deficiencies and Plan of Correction**

| (X1) Provider/Supplier/CLIA ID Identification Number: |
| (X2) Multiple Construction |
| A. Building: | |
| B. Wing: | |

<table>
<thead>
<tr>
<th>(X3) Date Survey Completed</th>
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<tr>
<td>09/10/2013</td>
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**Name of Provider or Supplier**

**Street Address, City, State, Zip Code**

<table>
<thead>
<tr>
<th>(X4) ID Prefix TAG</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
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<tr>
<td>U7037</td>
<td>Continued from page 7 emergency lighting units in proper working order.</td>
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Findings include:

During facility tour on 9/9/13, the "test" button was activated on the battery-powered emergency lights in the following areas, but the lights did not illuminate:

This finding was verified with Staff #1 on 9/10/13.
T2011—751.2(h) ORGANIZATION AND ADMINISTRATION. Operator

Based on document review and interview, the operator does not ensure the appointment of medical staff along with the assignment of clinical privileges and review of such appointments every

This deficiency was due to a lack of understanding of the credentialing and reappointment process. I believed that meant the physicians were appropriately licensed in New York State, had up to date DEA, Infection Control and Malpractice Insurance and did not realize that all physicians working at our facility required a formal review and reappointment every

PROVIDER’S PLAN OF CORRECTION

will now implement a formal credentialing/recredentialing process for new and existing physicians. This will consist of a request for renewal of clinical privileges, a delineation of those privileges (i.e., first trimester abortion, second trimester abortion, follow-up exam, etc.), CV, CME and peer review.

This shall be monitored as following: the Committee already reports to the Committee quarterly and will now state when each physician is due for reappointment and whether there are any concerns about privileges, etc.

(X5) COMPLETE DATE

This shall be implemented October □ 2013 (next □ Committee Meeting)
Based on document review and interview, the operator does not ensure that all facility policies and procedures are reviewed at least annually and revised as necessary. There was no evidence of review or revision of the policy and procedure manual for the laboratory or program.

These deficiencies were due to a lack of understanding of correct record keeping. Although we hold an mandated Class at which we show a NYS DOH approved video, give, grade and collect a written test on the material—we did not keep a separate log documenting these meetings. Attendance at the meeting and passing grade for the test was placed in each employee’s file. was inspected by the NYS DOH in April 2013. Of the twelve Fundamental Practices evaluated, were deemed “Fundamental Standard of Practice has been met”, were “partially met” and the CLEP Plan of Correction was submitted and accepted on May 1, 2013. We did not know that Laboratory Policies and Procedures were also to be part of the manual.

**PROVIDER’S PLAN OF CORRECTION**

will now do the following: An log has been created. In this log are the dates and attendance at the annual mandatory session, the test questions at each particular session and the passing grades of each employee. Further, the Nursing Supervisor will attest in writing, annually, that each employee who is required to attend this session has done so and passed the test—this will be part of the log. All new clinical hires who are mandated to watch the video have had the attestation placed in their files—in the future a copy will be placed in the Class log.

This shall be monitored as following: the Committee already reports to the Committee quarterly and will now state whether or not this log is up to date and reflects that each clinical employee has attended the class and passed the test.

Laboratory Policies and Procedures will be placed in the Policies and Procedure Manual and be reviewed annually.

This shall be monitored by monitoring the Operator’s signature at the bottom of each document.

(XS) COMPLETE DATE

This shall be implemented October 2013 (next Committee Meeting).
Based on document review, personnel file review and interview, the facility does not ensure that [redacted] at the facility has proof of completion of on-the-job training to perform such duties.

This deficiency was an administrative oversight. [redacted] Registered Nurse Staff #3, was originally trained at a [redacted] approved site in [redacted], NY. [redacted] skills have been verified by the Medical Director many, many times over the past [redacted] years. Additionally, [redacted] skills were considered so superior that the [redacted] of [redacted] contracted with us for the past [redacted] years to have [redacted] and its’ Medical Director had abundant confirmation of Staff #3 skill set and omitted the necessary proficiency verification.

PROVIDER’S PLAN OF CORRECTION

The Medical Director of [redacted] will provide training to Staff #3. 50 cases will also be observed and reviewed by the Medical Director for accuracy and proficiency and written documentation of both will be placed in her personnel file.

Any staff member who is trained in ultrasound by Staff #3 will have this training verified for accuracy and proficiency by the Medical Director.

This shall be monitored by an annual review of staff job orientation, training and proficiency.

(X5) COMPLETE DATE

This shall be implemented by October 30, 2013
Based on interview, the operator \[\text{was aware of the need for such consultation and had contracted with \[\text{in 2010 for this. This was a very extensive Medical Record Review completed on June 2011 which was to help comply with WHO medical record documentation rules, CMS documentation guidelines and NYS Medicaid rules for Article 28 clinics. Although this review was very detailed, we did not realize it did not meet the above regulation as it became more concerned about proper coding and revision of the chart itself. Additionally, it was not repeated annually due to cost issues.}}\]

\textbf{PROVIDER'S PLAN OF CORRECTION}

We have contracted with \[\text{to provide yearly chart review and education services to \[\text{$\ldots\ldots$}. Further we have ascertained that as part of the staff providing the review the \[\text{has the degree of \[\text{confirms that this will be a medical record review. This contract was signed September$\ldots$ 2013. There will be a review of 2012 and 2013 this year and then yearly.}}\]

This shall be monitored by an annual report verifying this chart review.

\textbf{(X5) COMPLETE DATE}

This was already implemented on September$\ldots$ 2013

\textbf{Americans United for Life}
Based upon document review and interview the operator...  

The Medical Director...  

...It was then difficult to find an appropriate replacement. No new medications were employed during the period...  

PROVIDER'S PLAN OF CORRECTION

This will be monitored by having the contracted pharmacist present medication issues at the quarterly... Meetings.

(X5) COMPLETE DATE

This will be implemented on October 2013.
U7036—702.3 (a) FIRE AND SAFETY

Based on observation and interview, the facility does not maintain all space free of hazards. There were three areas in the [redacted] that contained [redacted] waste.

This waste was generated during [redacted] concluded in [redacted] 2013 and during [redacted] of [redacted] on [redacted]. We did not intend to leave this waste in the [redacted].

PROVIDER’S PLAN OF CORRECTION

[redacted] has contracted with [redacted] the licensed contracting company performing the [redacted] renovations, to remove all cited waste from [redacted].

This will be monitored by inspection after the scheduled removal.

(XS) COMPLETE DATE

This will be implemented by November 1, 2013
Based on observation and interview, the facility does not conduct 30-day fire extinguisher inspections, as evidenced for 4 of 4 fire extinguishers.

Based on document review, observation and interview, the facility does not maintain the fire alarm system, as evidenced that there is not evidence that all smoke detectors in the facility are inspected and tested.

Based on observation and interview, the facility does not maintain 4 of 5 battery-powered emergency lighting units in proper working order.

Re: the fire extinguishers—had these supplied and inspected annually by a licensed dealer but had not conducted our own monthly inspection.

Re: the smoke detectors—has 7 smoke detectors connected to and an inspection had occurred on March 2013. However, we had placed 9 additional battery powered detectors which were not tested or inspected by

Re: the emergency lighting units—has been aware of the emergency lighting unit issue but obtaining the correct batteries was very difficult due to supplier issues.

PROVIDER'S PLAN OF CORRECTION

The fire extinguishers are now inspected on a monthly basis. This will be monitored by a monthly walk-through review.

The smoke detectors not connected to will be taken down. This will be monitored by a final inspection after removal.

Despite renewed efforts to obtain the batteries necessary for the emergency lighting units, none have been found. It appears that, as has an emergency generator, we may not be required to have these emergency lighting units. A Inspector will be on premises one day between October 2013 to inspect the electric work of the and will solicit his opinion on the emergency lighting units. If they are still deemed necessary, we will replace them with units whose batteries can be obtained. This will be monitored by a final report on the matter made by November 2013.

(X5) COMPLETE DATE

This will be implemented by November 2013.
RE: Article 28 D&TC Survey-completed September 10, 2013
Status of Plan of Correction

Dear [Name]

The Plan of Correction dated October 10, 2013 which you submitted in response to the Statement of Deficiencies dated October 4, 2013 has been reviewed by this office and is acceptable.

This office reserves the right to re-survey for compliance in the future. Acceptance of this Plan of Correction does not preclude any additional administrative action by this Department.

If you have any questions, please call [Contact Number]. Thank you.

[Signature]
Program Director
Hospitals and Diagnostic & Treatment Centers Program

cc: [Contact Information]
October 23, 2013

Re: Failure to comply with [redacted] approved for [redacted]

Dear [redacted]

On October 1, 2013 this office issued a Statement of Deficiencies in connection with the subject referenced above. On October 15, 2013 the facility submitted a Plan of Correction (POC). An addendum was submitted on October 22, 2013.

Review of the POC reveals it is acceptable, as noted on the enclosed form. Please continue implementation of the plan as this office will monitor compliance during future surveillance activities.

The cover letter for your October 15, 2013 POC mentions consolidation of administration services at [redacted]. This matter requires the attention of the Department’s Bureau of Project Management so that your [redacted] operating certificate may be corrected. Accordingly, please send a letter requesting the [redacted] of your [redacted] from the [redacted] to the following individual and address:

[redacted]

Should you have any questions, please contact me at [redacted].
<table>
<thead>
<tr>
<th>TAG #</th>
<th>CITATION</th>
<th>FINDING</th>
<th>COMMENTS/REQUIREMENTS</th>
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<td>T2006</td>
<td>751.2 ORGANIZATION AND ADMINISTRATION Operator</td>
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### Staffing September, 2013 through December, 2013

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<td>10am-3pm</td>
<td>(Advance Practice Clinician), (Patient Care Advocate II), (Support Associate II)</td>
</tr>
</tbody>
</table>

We are providing the following services to new and established patients:
- ST Infection Checks, Pregnancy Tests, Pre-op
- Birth Control Start- with referral list for continuing services elsewhere, Depos, FPBP, PE
County STI Testing 2013 advertising, publicity and community outreach

Advertising (paid placement)

Publicity (earned media)
Distributed news release to:

Published:

Community Outreach
Educators distributed and will continue distributing handouts promoting the County STI testing does education and outreach events at college (campus), schools, and other organizations in the community.
STI testing is quick, easy, and confidential.

- STI testing can be as simple as peeing in a cup - for men and women.
- HIV oral test with results in just 20 minutes.

Did you know?

- The most common symptom of a sexually transmitted infections is no symptom.

- As many as one in two sexually active young people will get an STI - and most won't know it. If you're having sex, you might be at risk. Get tested. It's quick, easy, and confidential.

- Undiagnosed and untreated, STIs can cause serious health problems.

- All STIs can be treated and most can be cured.
STI testing

STI testing is quick, easy, and confidential.

- STI testing can be as simple as peeing in a cup - for men and women.
- HIV oral test with results in just 20 minutes.

Did you know?

- The most common symptom of a sexually transmitted infections is no symptom.
- As many as one in two sexually active young people will get an STI - and most won’t know it. If you’re having sex, you might be at risk. Get tested. It’s quick, easy, and confidential.
- Undiagnosed and untreated, STIs can cause serious health problems.
- All STIs can be treated and most can be cured.
to:

Hospital BML

2013

Cc:

Show Details

Dear [Name],

In response to your letter dated [Date] concerning [Detailed Issue], attached please find our Plan of Correction including some relevant background information regarding this issue. Please be assured that we sought guidance and understood that we were acting according to that guidance in executing these actions. Even so, we know that it is our responsibility to understand and abide by the NYS Department of Health regulations regarding [Specific Requirement] and that we did not fully meet these requirements. Our Plan of Correction will ensure that this does not happen again.

Should you have any questions about the background or implementation of the Plan of Correction, please contact me directly at [Phone Number].

Sincerely,

[Signature]

[Company Name]

10/16/2013
October 15, 2013

Dear [Name],

In response to your letter dated October 13, 2013 concerning [issue], we acknowledge our failure to comply with [details]. Attached please find our Plan of Correction including some relevant background information regarding this issue. Please be assured that [department] sought guidance and understood that we were acting according to that guidance in executing these [details]. Even so, we know that it is our responsibility to understand and abide by the NYS Department of Health regulations regarding the [issue] and that we did not fully meet these requirements. Our Plan of Correction will ensure that this does not happen again.

Should you have any questions about the background or [Plan of Correction], please contact me directly at [contact information].

Sincerely,

[Signature]
Y 000 INITIAL COMMENTS

NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A FOCUSED SURVEY CONDUCTED IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION MUST PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

T2006 751.2 ORGANIZATION AND ADMINISTRATION. Operator.

The operator shall be responsible for the establishment of policies and the management and operation of the center in compliance with all applicable laws, rules and regulations, including the provisions of this Chapter. The operator shall not enter into any agreement limiting such responsibility. The operator shall be responsible for ensuring that all of the requirements of this Chapter applicable to the center are met.

This Regulation is not met as evidenced by: Based on findings from document review and interview [ has not complied with the following regulation in Title 10 New York Codes, Rules and Regulations.

401 3 CHANGES IN EXISTING MEDICAL FACILITIES.

SEE ATTACHED BACKGROUND.
(g) No medical facility shall discontinue operation or surrender its operating certificate unless 90 days' notice of its intention to do so is given to the commissioner and his written approval obtained.

Specifically, in July and August 2013 of its annual report, submitted to and approved by the New York State Department of Health (DOH). Also, in the report submitted to the DOH, it failed to describe all services it provided at any time. Further, it did not facilitate transfer to other providers in the area before it initiated the transfer for care involved.

Findings include:

-- On 5/13, letters were submitted to the DOH for its approval, located at [Redacted]. The letters described procedures for the services at those dates and also provided an explanation of the deficiencies described by the DOH in letters dated 6/13.

-- In letters received on 7/13 and 8/13, the facility submitted letters for the period. The letters contained statements indicating the last visit at the facility was on 8/13 and at the facility was on 7/13. The facility had done this without notifying and obtaining...
T2006  Continued From page 2

approval from the DOH to change the previously established

-- On or about 2013, staff at the Local Health Department became aware that a contract to provide services to residents at its

plans to facilitate continued provision of the services to County residents had

-- During telephone followup by the DOH with the

had recently issued notices to

and to the media, identifying the

This was done approximately the  of July 2013. The

acknowledged that these actions were not in accordance with the time frames in the

by the DOH, and had

taken place without first

from the DOH to

also acknowledged that they did not first notify and interact with the

Response to “Failure to comply with [redacted] for [redacted] million”

Background:

At the time of the [redacted] to NYS DOH for its [redacted] (located at [redacted]), was undergoing significant change in its [redacted]. The [redacted] Board of Directors was in the process of [redacted], creating a new administrative structure with [redacted]. Previous to this, the [redacted] had shared responsibilities with some contracts signed and kept in the [redacted] and others in the [redacted]. As it happens, the STI testing was arranged through the [redacted] of [redacted].

The original [redacted] by [redacted] 2013 proposed [redacted] of [redacted] 2013. However, [redacted] was not able to meet all [redacted] for the [redacted] by that time and was put in the position of [redacted] with revised dates. During this process, as one of the [redacted] explained, advice was received from DOH to choose a later date for the [redacted] than what was actually anticipated so as to avoid having to go through missing the [redacted] again and then [redacted] with a new 3 month window. Whether there was a misunderstanding of the guidance given or just a misunderstanding of the regulation, it was thought that the actions taken to [redacted] the dates they were was according to the regulation. Then, when the [redacted] for the [redacted] were [redacted] in July and there was only a written acknowledgement and thank you at that time, it was thought that this communication supported the interpretation that it was OK to [redacted] before the date listed on the [redacted].

While awaiting the [redacted] from NYS DOH on its [redacted], the [redacted] retired on May [redacted] 2013 and the [redacted] located in [redacted], who was scheduled to [redacted] August [redacted] 2013, continued to work on the [redacted] with representatives of DOH. In briefing the [redacted] who started on July [redacted] 2013 and is based in [redacted] about the status of the [redacted], closures (particularly the [redacted]), the outgoing [redacted] explained his understanding of the situation as outlined above.

Unfortunately, the existence of the STI testing [redacted] came to the attention of the new [redacted] of County Dept. called on August [redacted] in relation to the public announcement of the [redacted] for August [redacted]. At that point, with the patients already notified of the [redacted] in a letter at [redacted], the new [redacted] proposed [redacted] on a [redacted] to let people know that it would be open for STI testing and family planning services. [redacted]. In [redacted] County agreed to the proposed [redacted] [redacted] but wanted [redacted] to stay longer than first proposed (although this would have [redacted]). The [redacted] had proposed to DOH that this period be limited to [redacted] but it will now keep the [redacted] open through [redacted] 2013 per [redacted] request. [redacted] will continue to provide education and
community outreach to let people in the community know about services available on the dates scheduled.

From the time of the decision to close the [redacted] center, [redacted] has worked with [redacted] to try to [redacted] from the [redacted] to [redacted]. Originally, it was thought that [redacted] would just take over services at the same time, but [redacted] continued to work with [redacted] in a timeframe that would allow [redacted] to find a way to [redacted] and will work with [redacted] going forward to coordinate communication about new services when [redacted] is finally determined and the date for services approved. [redacted] continues to provide [redacted] in the area, making people aware of the existing [redacted] where services can be accessed and that [redacted] will soon be [redacted] with [redacted] on this past the 12/1/13 [redacted] until the [redacted].

Plan of Correction:

1. [redacted] leadership has reviewed the State procedures for [redacted] and the misunderstanding that led to the decision to [redacted] on the [redacted]. The [redacted] has informed the [redacted] Leadership Team of the error and explained the [redacted] regulation at its 2013 Team meeting (minutes of the meeting are available). The Board Chair and [redacted] will inform the Board of the situation and explain the [redacted] at the [redacted] 2013 meeting. This will ensure that the organization will find itself in position [redacted] [redacted] The Board Chair and the [redacted] will be responsible for monitoring continued compliance.

2. The Board of [redacted] has already taken the action to consolidate the [redacted] offices of [redacted] in [redacted]. The new [redacted] is in the process of organizing and reviewing all administrative files to ensure there is a complete list of contracts readily available. This effort will be completed by the Administrative Services Manager by [redacted] 2013 and the [redacted] will be responsible for monitoring continued compliance.

3. Although [redacted] had notified clients of its [redacted] consulted the [redacted] County Public Health Dept. about keeping the site open [redacted] and making community outreach efforts to let people in the area know about the dates and services. Since the [redacted] has kept the [redacted] open and providing services to those who call or stop in at the [redacted] will continue to keep the [redacted] through the [redacted] 2013. The VP for Practice Management and VP for Patient Services have already scheduled the staffing for the dates the [redacted] will be [redacted] the [redacted] has scheduled the Educator to be in the community, and the [redacted] will be responsible for monitoring continued compliance.
October 1, 2013

[Redacted]

Re: Failure to comply with [Redacted] for [Redacted]

Dear [Redacted],

In electronic mail correspondence dated [Redacted], 2013, [Redacted] for [Redacted] located in [Redacted], identified a [Redacted] date of [Redacted], 2013. The [Redacted] for the [Redacted] identified a [Redacted] of [Redacted], 2013. In letters dated [Redacted], 2013, the New York State Department of Health (the Department) informed the facility [Redacted] the [Redacted] identified a [Redacted] on [Redacted], 2013.

In letters to the Department dated [Redacted], 2013, [Redacted] for the [Redacted] were [Redacted] and [Redacted], 2013, [Redacted] had [Redacted] the [Redacted] without first obtaining approval from the Department to change the [Redacted].

On [Redacted], 2013, this office became aware that [Redacted] also initiated [Redacted] of the [Redacted] on [Redacted], 2013, without obtaining approval from the Department to change the [Redacted].

A Statement of Deficiencies (SOD) addressing this issue is enclosed. Please submit a Plan of Correction (POC) to this office at the following address within 10 business days of receipt of this letter: [Redacted].

The POC should respond directly to the correction of each item identified, include a timetable for completion of the plan (see right side (X5) column on the SOD), and identify the person(s), by position, who are responsible for implementation and monitoring for continued compliance.

If you have any questions, please feel free to contact [Redacted].

Sincerely,

[Redacted]
**ACTS Complaint/Incident Investigation Report**

**PROVIDER INFORMATION**
- Name: [redacted]
- Address: [redacted]
- City/State/Zip/County: [redacted]
- Telephone: [redacted]
- License #: [redacted]
- Type: [redacted]
- Medicaid #: [redacted]
- Administrator: [redacted]

**INTAKE INFORMATION**
- Taken by Staff: [redacted]
- Location Received: [redacted]
- Intake Type: Complaint
- Intake Subtype: State-only, licensure
- External Control #: [redacted]
- SA Contact: [redacted]
- RO Contact: [redacted]
- Responsible Team: [redacted]
- Source: [redacted]

**COMPLAINANTS**

**RESIDENTS/PATIENTS/CLIENTS** - No Data

**ALLEGED PERPETRATORS** - No Data

**INTAKE DETAIL**
- Date of Alleged Event: [redacted]
- Time: [redacted]
- Shift: [redacted]

**Standard Notes:**
Patient was seen at the clinic on 8/12 for a pre-abortive exam. Ultrasound performed indicated a gestational age of 11 weeks and 4 days. Patient was 8 weeks and 4 days late. Patient was scheduled for an abortion. Procedure started at 10:45 AM and ended at 11:50 AM. Final examination of the patient revealed an estimated gestational age of 11 weeks. Physician ordered 2 mg of aripiprazole and was administered by 1st LPN at 10:48 AM. It was after the procedure was completed that patient began to have symptoms. physician ordered 1st LPN administer a second dose of aripiprazole. Physician instructed staff to call 911 for transfer to the 2nd LPN called 911 and notified the Medical Resident, with the assistance of the 1st LPN monitored patient. Patient's pulse was not registering. Patient's vital signs were recorded. The ambulance arrived within 10 minutes of call. 2nd LPN notified Emergency room at the hospital that patient would be arriving.

**Extended RO Notes:**

Extended CO Notes:

**ALLEGATIONS**
- Category: Other Services
- Subcategory: Outpatient Services
- Seriousness: Moderate

**Findings:**
Substantiated: State deficiencies related to the allegations are cited

**Deficiencies Cited:**
State-T-2008-ORGANIZATION AND ADMINISTRATION. Operator. (751.2(b))
ACTS Complaint/Incident Investigation Report

Deficiencies Cited: State-T-2055-ORGANIZATION AND ADMINISTRATION. (751.5 (e))
State-T-2114-ORGANIZATION AND ADMINISTRATION. (751.7 (d))
Details: inadequate management of the patient during a
abortion.

Findings Text:

Based on findings from document review and interviews, the care provided to Patient A in connection with a
abortion performed at the Medical Center did not meet
generally accepted standards of professional practice for patient safety. Up to date patient information and
necessary equipment / supplies were not immediately available for the procedure and management of any
complications that might occur. Also, during the emergency that did occur in this case, staff did not
and did not perform the facility's patient emergency procedures.

Findings include:

-- Review of Patient A's MR reveals the following information:

On 08/12/12, Patient A presented to the Medical Center for a medical abortion. An outdated ultrasound (US) report in the
MR indicates the patient's last menstrual period (LMP) was 10 weeks and 3 days prior - it states the
patient was 10 weeks and 3 days and " ... The report does not include all the information obtained for determining the age, and does not provide a clear explanation of why a

Physician progress notes (dated [redacted], later, 08/12/12) specifically describe or state the following information:

- An US performed in the MR on 08/12/12 indicated the patient was 11 weeks 3 days. The US would be performed at 11 weeks and 3 days.

- Procedure began in usual fashion ... However, the decision was made to [redacted].

- The procedure was performed, and the uterus was retrieved and examined. While that was being sought, the uterus was [redacted].

- At the completion of the procedure, the uterus was [redacted]. Examination did not reveal any abnormalities. [redacted] was [redacted] accounting for.

- The patient was given and the dose of oxygen was given and continued. A [redacted] was initiated. The MR lacks details about the [redacted].

- Progress notes by licensed practical nurse (LPN) #1, dated 08/12/12, state "Attempted to ... unable to get ABG [redacted] ... pulse monitoring continued until arrival of EMS.

- LPN #1 documented 911 was called at [redacted] minutes later, and that he/she called the emergency

- The policy and procedure (P&P) titled [redacted] dated 2010, indicates that in an emergency, such as the

patient's [redacted] must be documented every minute until the situation has stabilized or the patient is

transferred. The P&P also indicates that when uterine [redacted] occurs, [redacted] will be provided by

ACTS Complaint/Incident Investigation Report

In summary, in this abortion case involving complication of

* The US report was visually difficult to read, did not contain complete information and also lacked the date of the procedure and the complete signature of the __________.

* There is no indication the __________ was rechecked at the abortion visit as directed in the pre-abortion US report.

* Staff did not verify the availability of all necessary equipment prior to the start of the procedure.

* A __________ was not available for back up when the __________ did not work.

* The patient's __________ were not carefully monitored and recorded __________ during the emergency. __________ was not __________ to the patient.

Based on findings from document review and interview __________ staff were not complying with the facility policy and procedure (P&P) regarding the performance of ultrasounds (USs). In reports of US examinations done by __________ the reports lack evidence oversight was provided during the procedure and that the interpretation the __________ provided was reviewed and finalized by a physician. Also, in Ultrasound (US) reports reviewed in medical records (MRSs), complete details as well as the signature of an interpreting physician were lacking.

Findings include:

-- Per review of the facility P&P titled __________ dated __________, it indicates an US may only be performed by an affiliate-employed certified sonographer... or an affiliate physician privileged in the performance of gynecologic USs. It also indicates that personnel interpreting and providing final reports for gynecologic USs must be affiliate physicians.

Also, the P&P indicates that initial training for an US sonographer must include a combination of direct observation of scanning technique and submission of the scans to the program director (or designee) for review. It states that a minimum of 20 scans must be completed by the trainee.

-- Review of Patient F's MR reveals __________ performed __________ and signed the reports with the words __________ after his/her signatures. There is no documentation indicating that another practitioner or physician reviewed the __________ or reviewed the interpretation the __________ provided on the reports.

-- Review of the MRSs for Patients __________ reveals the following lapses in the reports of US examinations performed by ____________

* Lack evidence the findings were interpreted by an affiliate physician (i.e., physician signatures are lacking);

* Lack the date of the procedure;

* Contain sonographer signatures that are __________.
ACTS Complaint/Incident Investigation Report

In the report, certain to US examinations done for pre-abortion. The following lapses are noted in those reports:

- Lack information responding to the question of whether [redacted] was detected;
- Lacks description of the number of [redacted] and
- Lack the [redacted].

Based on findings from document review and interview, information recorded in [redacted] medical records (MRs) was incomplete. The MR for Patient A lacks complete information regarding an [redacted] that was [redacted] during an emergency (see pertinent findings in tag T2031). Also, the US reports in Patient A's and other patients' MRs lack complete information and legible signatures (see the findings in tags T2031 and T2056).

---

**SURVEY INFORMATION**

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Intakes Investigated: [redacted] (Received: 10/17/2012)

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**SUMMARY OF CITATIONS:**

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State - Link to This Intake

T2008-ORGANIZATION AND ADMINISTRATION. Operator.

T2114-ORGANIZATION AND ADMINISTRATION.

T2058-ORGANIZATION AND ADMINISTRATION.

State - Not Related to any Intakes

T0000-INITIAL COMMENTS

---

EMTALA INFORMATION - No Data

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Americans United for Life
### ACTS Complaint/Incident Investigation Report

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AGENCY REFERRAL

Agency
Island Peer Review Organization (IPRO)

Contact Name

Date Referred
12/18/2012

Due Date

Agency Visit

Report Received
01/30/2013

LINKED COMPLAINTS - No Data

DEATH ASSOCIATED WITH THE USE OF RESTRAINTS/SECLUSION - No Data

Reason for Restraint:

Cause of Death:

NOTICES

Notification:

Date
10/17/2012

Type
Acknowledgement to Complainant

Party
Central Office

Method
E-Mail

PROPOSED ACTIONS

Proposed Action
State Only Actions
POC (No Sanction)

Proposed Date
04/29/2013
04/29/2013

Imposed Date
04/29/2013
04/29/2013

Type
Federal
State

Closed: 01/13/2014

Reason: Paperwork Complete

END OF COMPLAINT INVESTIGATION INFORMATION
May 6, 2013

RE: Complaint # [Redacted]  
Corrected Statement of Deficiencies

Dear [Redacted],

In connection with the complaint referenced above, on April 29, 2013, this office issued a Statement of Deficiencies (SOD) to your facility. The purpose of this letter is to provide a corrected copy of the SOD. You will note that the reference to two tag numbers on page 7 of the SOD has been corrected. Previously, the SOD contained two references to Tag T2031. Tag T2031 has been changed to T2008 in both references. Please accept my apologies for any inconvenience this may have caused.

The time frame for submission of a Plan of Correction remains the same, no later than 10 business days from receipt of the April 29, 2013 letter.

If you have any questions, please feel free to contact [Redacted].

Sincerely,

[Redacted]

Attachment
NEW YORK STATE DEPARTMENT OF HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CILA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION
A. BUILDING: ______________________
B. WING ______________________

(X3) DATE SURVEY COMPLETED
C 11/05/2012

NAME OF PROVIDER OR SUPPLIER ______________________ STREET ADDRESS, CITY, STATE, ZIP CODE ______________________

(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

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| T 000 | PF[REDACTED] OPERATING CERTIFICATE [REDACTED]

NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF COMPLAINT [REDACTED] THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

T2008 751.2 (b) ORGANIZATION AND ADMINISTRATION. Operator.

The responsibilities of the operator shall include but not be limited to:

(b) ensuring that all patients receive quality health care and services provided in accordance with generally accepted standards of professional practice.

This Regulation is not met as evidenced by:

Based on findings from document review and interviews, the care provided to Patient A in connection with a [REDACTED] abortion performed at the [REDACTED] did not meet generally accepted standards of professional practice for patient safety. Up to date patient information and necessary equipment / supplies were not immediately available for the procedure and management of any complications that might occur. Also, during the emergency that did occur in this case, [REDACTED] staff did not [REDACTED] and [REDACTED] per the facility's patient care policy.

Office of Health Systems Management

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE ______________________

STATE FORM ______________________

TITLE ______________________

(If continuation sheet 1 of 7)
T2008 Continued From page 1

emergency procedures.

Findings include:

- Review of Patient A's MR reveals the following information:

  On 08/21/12, Patient A presented to the hospital for a "for a documented abortion. An undated ultrasound (US) report in the MR indicates the patient's last menstrual period (LMP) was in weeks and days prior - it states the LMP was weeks and days" and "The report does not include all information obtained for determining the LMP and does not provide a clear explanation of why a repeat LMP was necessary. The signature of the staff member who performed the LMP is.

  Physician progress notes (dated later, 08/12) specifically describe or state the following information:

    - An US performed in the patient's notes on 08/12 indicated the LMP was weeks and days. The patient would then be weeks and days."

    - "Procedure began in usual fashion ... However, after several days, decision was made tog."

Office of Health Systems Management
STATE FORM

Americans United for Life
At the completion of the procedure, examination did not reveal any problems and were noted. The uterus was palpated based on size. A dose of 1000cc of Lactated Ringer's was given and packed was performed. The patient was discharged but when emergency medical services (EMS) was called, a second dose of 1000cc Ringer's was given and continued. A medical resident established an 18 Fr central line and an arterial line was initiated. (The MR lacks details about the procedure, i.e., what medications used, lasted, etc.) as well as the patient's condition prior to EMS transport of the patient to a hospital.

Progress notes by licensed practical nurse (LPN) #1, dated 08/24/12, state "Attempted to transport patient, unable to get her to the OR until arrival of EMS. Last seen at immediately post procedure -"

LPN #2 documented 911 was called at 10:30 AM (arriving minutes later), and that he/she called the emergency room to alert the staff the patient was on her way via ambulance.

- The policy and procedure (P&P) titled dated 2010, indicates that in an...
T2008 Continued From page 3

emergency situation the patient's [redacted] must be documented every [redacted] minutes until the situation has stabilized or the client is transferred. The P&P also indicates that when [redacted] occurs, [redacted] will be provided by [redacted] at [redacted].

In summary, in this [redacted] abortion case involving complication of [redacted]

* The US report was visually difficult to read, did not contain complete information and also lacked the date of the procedure and the complete signature of the proceduralist.

* There is no indication the [redacted] was rechecked at the abortion visit as directed in the pre-abortion US report.

* Staff did not verify the availability of all necessary equipment prior to the start of the procedure.
T2008  Continued From page 4

* A [redacted] was not available for back up when the [redacted] did not work.

* The patient's [redacted] were not carefully [redacted] and [redacted] during the emergency.

* [redacted] was not [redacted] to the patient.

T2056  751.5 (a) ORGANIZATION AND ADMINISTRATION

Operating Policies and Procedures.

The operator shall ensure:

(a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice.

This Regulation is not met as evidenced by:

Based on findings from document review and interview, [redacted] staff were not complying with the facility policy and procedure (P&P) regarding the performance of ultrasounds (USs). In reports of US examinations done by a [redacted], the reports lack evidence oversight was provided during the procedure and that the interpretation the [redacted] provided was reviewed and finalized by a physician. Also, in ultrasound (US) reports reviewed in medical records (MRs), complete details as well as the signature of an interpreting physician were lacking.

Findings include:

-- Per review of the facility P&P titled [redacted] dated 2011, it indicates an US may
only be performed by an affiliate-employed certified sonographer ... or an affiliate physician privileged in the performance of gynecologic US. It also indicates that personnel interpreting and providing final reports for gynecologic USs must be affiliate physicians.

Also, the P&P indicates that initial training for an US sonographer must include a combination of direct observation of scanning technique and submission of the scans to the program director (or designee) for review. It states that a minimum of 20 scans must be completed by the trainee.

-- Review of Patient F's MR reveals performed USs and signed the reports with the words after his/her signatures. There is no documentation indicating that another practitioner or physician observed the or reviewed the interpretation the provided on the reports.

-- Review of the MRs for Patients reveals the following lapses in the reports of US examinations performed by who were certified US sonographers:

* lack evidence the findings were interpreted by an affiliate physician (i.e., physician signatures are lacking);
* lack the date of the procedure;
* contain sonographer signatures that are either illegible or are covered.

In the reports pertain to US examinations done for pre-abortion gestational dating. The following lapses are noted in those reports:
<table>
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<th>T2056</th>
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<tr>
<td>☐ lack information responding to the question of whether _______ was detected;</td>
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<tr>
<td>☐ lacks description of _______ present; and</td>
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<td>☐ lack the _______</td>
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<th>T2114</th>
<th>751.7 (d) ORGANIZATION AND ADMINISTRATION.</th>
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<tr>
<td>Medical record system. The operator shall:</td>
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<td>(d) ensure that the medical record for each patient contains and centralizes all pertinent information which identifies the patient, justifies the treatment and documents the results of such treatment.</td>
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This Regulation is not met as evidenced by: Based on findings from document review and interview, information recorded in __________ medical records (MRs) was incomplete. The MR for Patient A lacks complete information regarding an __________ during an emergency (see pertinent findings in tag T2008). Also, the US reports in Patient A’s and __________ other patients’ MRs lack complete information and legible signatures (see the findings in tags T2008 and T2056). |
Annette, this note is transmit the response including a cover letter, the plan of correction and back-up documents for complaint # . I appreciate electronic confirmation of receipt. Please let me know if for any reason you have difficulty opening this zip file. We will also deliver to the DOH on Monday a memory stick with the same documents if that proves easier to open. You can reach me at the phone number below or over the weekend on my cell phone number:  

Many thanks.
**New York State Department of Health**

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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**NAME OF PROVIDER OR SUPPLIER**

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**SUMMARY STATEMENT OF DEFICIENCIES**

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**PROVIDER'S PLAN OF CORRECTION**

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**T 000 INITIAL COMMENTS**

- **PF:**
  - OPERATING CERTIFICATE

  **NOTE:** THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF COMPLAINT. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.

**T 2008 751.2 (b) ORGANIZATION AND ADMINISTRATION. Operator.**

- The responsibilities of the operator shall include but not be limited to:
  - (b) ensuring that all patients receive quality health care and services provided in accordance with generally accepted standards of professional practice.

- This Regulation is not met as evidenced by: Based on findings from document review and interviews, the care provided to Patient A in connection with an abortion performed at the facility did not meet generally accepted standards of professional practice for patient safety. Up to date patient information and necessary equipment / supplies were not immediately available for the procedure and management of any complications that might occur. Also, during the emergency that did occur in this case, staff did not...

Office of Health Systems Management

**LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S STATE FORM**

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<th>EXPIRATION DATE</th>
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<td>5/23/2013</td>
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**Americans United for Life**
May 10, 2013

Re: Complaint

Dear [Name],

I am writing in response to your April 29, 2013 letter regarding the Summary Statement of Deficiencies with respect to the above-referenced complaint.

We have endeavored to respond to all the deficiencies outlined in your letter. We have reviewed and evaluated the deficiencies cited in the summary statement and have taken steps to correct the deficiencies.

We have also proactively hired additional medical and clinical professionals. We have hired a [Name] (please see the attached cv) who recently [position] and a [Name] (please see the attached cv), both of whom have been trained to reinforce lessons learned.

We have strengthened our emergency procedures for the entire provider team including physicians, LPNs, RNs, and NPs, PAs, and we have directed our medical director to carry out continuous in-service training for clinicians. We have attached a Plan of Correction which indicates the steps we have taken and the steps which we will put in place...
We do, however, wish to correct two specific findings in the Statement of Deficiencies which allege that [redacted] failed to comply with its own internal policies and procedures related to ultrasound training, interpretation and privileging.

1. **Compliance with that Policy:** We have attached a policy which was revised in [redacted] 2011 and was implemented in [redacted] 2011 (the "2011 Policy"). A revised policy was drafted in [redacted] 2012. However, that policy did not actually go into effect until [redacted] 2012 (the "2012 Policy"). Although both of these policies were provided to the lead inspector from your office, the 2011 Policy — and not the 2012 Policy — was the one which was in effect at the time Patient A underwent the [redacted] abortion procedure on [redacted] 2012. Of note, [redacted] only performs ultrasound procedures in the [redacted] pregnancy. The 2011 Policy outlines the specific duties of the ultrasound provider in providing these services, and specifically permits [redacted] to interpret the ultrasound findings. Therefore, we believe that [redacted] followed the procedures set forth in the applicable 2011 Policy at the time the ultrasound was performed on Patient A. The more complex formulary specified in [redacted] of the 2012 Policy was mistakenly relied upon by the Department in its Statement of Deficiencies with respect to this complaint (see TAG T2056, pp. 5-6). The 2012 Policy covers all forms of ultrasound services, including ultrasound services [redacted] pregnancy. These provisions are not applicable since we do not perform ultrasound services [redacted] pregnancy. Accordingly, we respectfully request that the Department correct the statement in the second paragraph of TAG T2056 on page 5 of the Statement of Deficiencies which states that [redacted] staff was not complying with the facility policy and procedure regarding the performance of ultrasounds.

2. **Training and Privileging for Sonography (TAG T2056, page 6):** [redacted] at [redacted] who perform ultrasounds are trained by [redacted] Medical Director, who is the director of ultrasonography for [redacted]. Following this training, the [redacted] must perform ultrasound procedures under peer review according to a specific evaluation sheet. Once all these steps are complete, the individual is recommended by the Medical Director to [redacted] Board for ultrasound privileges. We respectfully request that this portion of the findings be revised before the final report is issued on this case.

Sincerely,

[Redacted]

Attachments:

[Redacted]
Plan of Correction to Complaint

ID Prefix Tag: T2008

Statement of Deficiency

Per ACOG guidelines referenced in [redacted], ultrasound established dates should take preference over LMP when the discrepancy was indicated in this case. There wasn’t a deviation from established policy.

According to policy, [redacted] is the most accurate indicator of gestational age. Required components were met policy. The ultrasound preprogrammed software for [redacted]. There wasn’t a deviation from established policy.

The Ultrasound image had the [redacted] but the [redacted] did not.

[Redacted] will be reported to the [redacted] Committee.

Signature of staff who performed the Ultrasound is [redacted].

No indication that the [redacted] was rechecked at the abortion visit as directed in the pre-abortion report.

5/13/13 - Staff training
8/12/13 - Audit form and then audit quarterly by lead clinician with a report to [redacted] Committee.

8/12/13 - Audit form and then audit quarterly by lead clinician with a report to [redacted] Committee.

8/12/13 - Audit form and then audit quarterly by lead clinician with a report to [redacted] Committee.

Americans United for Life
Statement of Deficiency

Staff did not verify the availability of all necessary equipment prior to the start of the procedure.

A [redacted] was not available for back up when the [redacted] did not work.

The patients were not [redacted] and [redacted] during the emergency.

[Redacted] was not [redacted] to the patient.

Plan of Correction

[Redacted]

Implementation and Monitoring

Managers to conduct Emergency drills and audit every 6 months with a report to the [redacted] Committee.

In [redacted] 11/12

Reviewed usage of [redacted] with staff.

12-Nov

Regional Managers to conduct Emergency drills and audit every 6 months with a report to the [redacted] Committee.


[Redacted] 03/31/2012
Plan of Correction to Complaint

ID Prefix Tag: T2056

Statement of Deficiency

Per review of the facility P&P titled [redacted], dated 2011, it indicates an US may only be performed by an employee certified sonographer or physician privileged in the performance of gynecologic US. It also indicates that personnel interpreting and providing final reports for gynecologic US must be physicians.

Also, the P&P indicates that initial training for an US sonographer must include a combination of direct observation of scanning technique and submission of the scans to the program director, [or designee] for review. It states that a minimum of 20 scans must be completed by the trainee.

Review of Patient F's MR reveals performed USs and signed the reports with the words [redacted] after his/her signature. There is no documentation indicating that another practitioner or physician observed the trainee or reviewed the interpretation the [redacted] provided on the reports.

In accordance with policy, [redacted] 2011, personnel, staff who provide ultrasound services, are trained and proctored. This demonstrates adherence to the policy in that, trainees complete the [redacted] accredited training.

The trainees participate in hands-on training with appropriately trained and skilled personnel and are proctored by direct observation in the performance AND/OR interpretation of ultrasound until competence is reached and is determined by staff who are privileged to interpret. This is demonstrated after 20 scans have been successfully completed and reviewed by Ultrasound Director. All scans that a trainee completes are reviewed internally. [Redacted] also scans images to our other clinics so a NP, PA or MD may review a scan at a [redacted] and provide input.

Plan of Correction

In accordance with [redacted] policy, the personnel that may perform Ultrasound in Abortion Care are, non-licensed personnel, licensed nurses, clinicians, certified sonographers and physicians. Personnel who perform Ultrasound are, licensed nurses, clinicians and physicians. Staff who may interpret Ultrasound are, clinicians and physicians. Only clinicians and physicians interpret ultrasounds at [redacted].

Implementation and Monitoring

[Redacted] is in compliance.

Review of the MRs for Patient [redacted] reveals the following lapses in the reports of US examinations performed by [redacted] certified US sonographers

[Redacted] is in compliance.
Ultrasound may be provided as part of the following services:

1. Medical and Surgical Abortion
2. Evaluation of Early Pregnancy / Management of Early Pregnancy Complications
3. Pregnancy Diagnosis
4. Prenatal Care
5. IUC insertion and/or localization
6. Other Gynecological Conditions

Approval — Approval for a clinical service includes approval to provide ultrasound as part of that service. Separate approval is not required.

Performance vs. interpretation of ultrasound

1. Performance of the ultrasound is the act of doing the examination — taking the measurements, creating a printed image, and reporting the findings for interpretation.
2. Interpretation of the ultrasound is reviewing the findings, providing an impression or conclusion, and approving and signing the final written report.

Client viewing of ultrasound images — Any client who undergoes an ultrasound at the affiliate must be offered the opportunity to view the ultrasound image.

1. Clients who request a copy of the ultrasound image should be accommodated whenever possible.
2. Please refer to the documentation, below.

First Trimester — examination of pelvis in first trimester of pregnancy includes evaluation:

1. for presence and location of gestational sac
2. for presence or absence of yolk sac or embryo, and crown-rump length whenever possible
3. for presence or absence of cardiac activity
4. for fetal number
5. of uterus, adnexal structures and cul de sac, if clinically indicated

Second or Third Trimester — examination of pregnancy beyond the first trimester includes:

1. all components of first trimester ultrasound, plus
2. placental localization
3. gestational dating, using at least one, and preferably two fetal biometric parameters
4. in third trimester, prenatal clients
   • estimated fetal weight
   • amniotic fluid evaluation
   • fetal position
● placental grade

Gynecologic diagnostic ultrasound — ultrasound of the non-pregnant female pelvis includes evaluation of the:
1. uterus and myometrium
2. cervix
3. cul-de-sac
4. ovaries
5. fallopian tubes (including absence of visualization)
6. endometrium and endometrial thickness
7. variations from normal size should be accompanied by measurements

Limited Ultrasound — performed when a specific question requires investigation (see below for specific indications for limited ultrasound for specific services)

Real-time Scanners — Real-time scanners should be utilized with an abdominal and/or vaginal approach. A transducer of appropriate frequency (3.5 MHz or higher for abdominal; 5 MHz or higher vaginally) should be used.

Vaginal Probes — must be disinfected between use and must always be covered with a condom or other disposable protective sheath when inserted into the vagina.

Ultrasound Capacity — Affiliates providing ultrasound must have the capacity to perform abdominal as well as vaginal ultrasound.

Program director — each affiliate providing ultrasound services must have a program director who must be a physician or advance practice clinician. The program director must
1. Complete the ultrasound training in abortion care (either by completing the whole course or completing the
2. Complete the
3. Supervise the affiliate program and assure compliance with
4. Supervise and assure compliance with the quality improvement standards. (See
5. Grant clinical privileges. The program director may designate a clinician(s) who may grant clinical privileges. Any clinician involved in granting privileges must pass the proficiency test listed above.

Staff who provide ultrasound services
1. Both licensed and non-licensed personnel may be trained in the provision of ultrasound where allowed by state and local law.
   - Non-licensed staff
     o May perform ultrasound for certain services. See below for details.
Non licensed staff **must** not interpret ultrasound.

- **Must** successfully complete a skills checklist before they may perform ultrasound.
- **Licensed staff**
  - May perform and/or interpret ultrasound examinations. See below for information on which licensed staff may interpret ultrasound for specific services.
  - **Must be granted clinical privileges to perform and/or interpret ultrasound.** Clinical privileges should include separate categories for performing and interpreting each type of ultrasound listed in this section and defined in [insert definition here] below.

2. Training and Proctoring — All staff (including contractual employees) that perform and/or interpret ultrasounds **must**

- **complete the** [insert training program name] **OR pass the** [insert exam name] **OR demonstrate completion of an equivalent program**
- participate in hands-on, supervised training **OR demonstrate previous hands-on training** (not required for staff who interpret only)
- Hands on training may be performed by any appropriately trained and skilled personnel.
- be proctored (direct observation in the performance and/or interpretation of ultrasound) until competence has been reached
- For personnel who will interpret ultrasound, proctoring **must** be done by staff who are privileged to interpret.

**FYI — Accessing the**

**Documentation** — of training, proctoring, privileges and completed skills checklists must be placed in personnel file.

**Specific Services** — see individual services below for specific personnel issues.

Every affiliate **must** have a quality improvement program. (See [insert quality improvement program guidelines] below.) The quality improvement program **must**

1. Ensure initial proficiency for staff.

Revised [insert date], Implemented [insert date] 2011
Confidential property of [insert organization name]
Document initial training and proficiency. (See [redacted]).

Process of initial training:
- **Must** include a combination of direct observation of scanning technique and submission of scans to program director (or designee) for review.
- A minimum of 20 scans **must** be completed by the trainee. The number of scans performed will vary by individual. Each trainee **must** do the number of scans that assures competency.
- Discretion on the part of the program director is allowed, especially in cases of trainees with past experience.

2. Evaluate and document ongoing proficiency.
- Identify problematic areas.
- Document a corrective action plan.
- Have a system in place to assess results of corrective actions.

3. Ensure complete evaluation of the Ultrasound program through
- Review of equipment, medical records and personnel charts.
- Evaluation of the results of any deficiencies with corrective actions / interventions.

4. Revisit corrective actions / interventions to determine outcome at regular intervals.

---

Every ultrasound examination **must** be documented and signed by the appropriate affiliate personnel. This may be accomplished by using a flow sheet or within the narrative report of the client encounter.

**Pre-Procedure Image** — For each pre-procedure ultrasound, a printed image or photograph **must** be taken and maintained as part of the client’s medical record.

**Intra or Post-Procedure Image** — When an intra- or post-procedure image is taken, it **must** be maintained as part of the client’s medical record.

**Written Report** — The written final report, whether provided by the affiliate or an outside facility includes:
1. name(s) of person(s) performing and interpreting the ultrasound
2. special techniques, equipment, media, or medications used, if any
3. whether exam was satisfactory with notation of limitations, if any
4. anatomic areas scanned
5. normal findings and/or abnormalities
6. diagnostic Impression
7. specific findings related to the purpose of the exam (e.g., intrauterine gestation/size, number, IUC) (see also Items [redacted] below, for documentation for specific types of ultrasound)
8. comparison with previous ultrasounds for the same condition, if applicable

**Clients and Ultrasound Images** — documentation in the client record **must** include if the client was offered the opportunity to see her ultrasound, her response to the offer, and if she was given a copy of the ultrasound image.
FYI — Options for viewing the ultrasound

Affiliates have shared that they most commonly offer women the option to view the ultrasound in one of two ways — a direct question to the client or indirectly as part of the client intake form. Either way is acceptable.

Document that the option was offered, whether or not the client chose to view the image, and that it was shown to her (if applicable).

Client preferences:
Do you want to see the ultrasound? ____ Yes ____ No
Do you want to know if there is more than one pregnancy? ____ Yes ____ No

If the client indicates yes to either question, the record can simply have a checkbox:

____ Client shown ultrasound image
____ Client given a copy of the image
____ Client informed of multiple pregnancies

Prior to the performance of ultrasound — the client must be signed or already present in the client’s record.

Limitations of the Ultrasound — The client must be informed of the limitations of the ultrasound being performed. For example, an ultrasound for pregnancy dating only would not be evaluating fetal anatomy.

1. Information may be given verbally.
2. It must be documented in the client’s medical record that the information was given.

Personnel

1. The following affiliate staff may perform or interpret first or second trimester or limited ultrasound after meeting training requirements described above and undergoing appropriate proctoring/privileging.
   - Performance of ultrasound — non-licensed personnel, licensed nurses, clinicians, certified sonographers and physicians
   - Interpretation of ultrasound — clinicians and physicians
2. Complex cases — when an abortion-related abnormality, condition, or complication is complex enough to require further ultrasound evaluation, i.e., the findings of the original ultrasound are unclear or exceed the privileges granted.
the clinician), the ultrasound must be interpreted by and usually* performed by
the following.
- An affiliate physician with ultrasound privileges related to abortion
or
- An out-of-affiliate radiologist or other physician with similar experience and
skill for consultation
or
- An emergency facility capable of evaluating and managing abortion-related
conditions
*In rare circumstances, when the physician is attending to the needs of the client, the
ultrasound may be performed by a privileged non-physician.

Documentation
1. All ultrasound examinations must be interpreted and co-signed by a privileged
clinician or physician.
2. See [blank] above, for specifics about the report.

Medication Abortion
1. Pre-abortion first trimester ultrasound is required. A limited post-abortion
ultrasound is required if pregnancy termination is not confirmed with serial BhCGs.
2. See [blank] for specific standards related to medication abortion and the use of ultrasound.
3. Whenever a discrepancy exists between the findings on an ultrasound examination
and the client’s clinical history, the responsible clinician/physician should repeat the
ultrasound procedure in order to confirm the initial findings. In most circumstances,
this does not apply to size/date discrepancies when the ultrasound dating is clear.

Surgical Abortion
1. First trimester Abortion
   - First trimester ultrasound must be performed in the following circumstances, when:
     o Accurate dating cannot be determined by bimanual pelvic
       examination or there is a discrepancy between size and dates.
     o There is a possibility that the client may not be pregnant.
     o There is suspicion that the client is beyond 13w 6d gestation.
     o The pelvic examination reveals an abnormality that might interfere
       with the safe performance of the abortion (e.g., adnexal masses,
       myomata, congenital uterine anomalies, hyperflexion of the
       uterus, severe retroversion).
   - Limited ultrasound
     o On-site availability of limited ultrasound is strongly encouraged but
       not required. When ultrasound is not available on site, a consultant
       relationship with a qualified provider in the community must exist
       for referral of clients as needed.
     o May be used intra-operatively or post-operatively to evaluate:
       ▪ suspected perforation
       ▪ cervical stenosis
       ▪ confirmation of the evacuation of multiple uterine components
         (septate and bicornuate uterus)
       ▪ completion of a procedure when fetal size is found to be greater
         than originally estimated
- postabortal problems, particularly in the evaluation of retained products of conception or a continuing intrauterine pregnancy
- immediate confirmation of completion of procedure when POCS are not clearly identified in early surgical abortion

2. Second trimester ultrasound must be performed prior to mid-trimester abortion.
3. Whenever a discrepancy exists between the findings on an ultrasound examination and the client's clinical history, the responsible clinician/physician should repeat the ultrasound procedure in order to confirm the initial findings. In most circumstances, this does not apply to size/date discrepancies when the ultrasound dating is clear.

Early Pregnancy Evaluation and Management of Early Pregnancy Complications
1. See [specific standards related to the use of ultrasound]
2. Whenever a discrepancy exists between the findings on an ultrasound examination and the client's clinical history, the responsible clinician/physician should repeat the ultrasound procedure in order to confirm the initial findings.

Types of ultrasound that may be performed
1. First trimester
2. Second trimester
3. Limited — may be used for:
   - actual or potential emergencies, for example, if the woman is bleeding
   - for confirmation of IUP and gestational dating only

Personnel and Documentation
1. Only the following affiliate personnel may perform ultrasound for the purpose of pregnancy diagnosis and gestational dating:
   - Performance of ultrasound — non-licensed personnel, licensed nurses, clinicians, certified sonographers, physicians
   - Interpretation of ultrasound — physicians and clinicians
2. See Subsection VI, above, for specifics about the report.

Ultrasounds that must be referred — Ultrasound examinations that must be referred to a qualified radiologist or perinatal specialist and must not be performed at the affiliate:
1. Required 18–20 week prenatal ultrasound to assess fetal anatomy
2. Specialized ultrasound for known or suspected fetal abnormalities or other complications including nuchal translucency screening (See [specific standards] for more information.)

Ultrasounds that may be performed at the affiliate
1. First trimester prenatal ultrasound
2. Standard second or third trimester prenatal ultrasound
3. Limited prenatal ultrasound (e.g. fetal heart tones are not audible with the transducer)
Personnel and Documentation
1. Only the following affiliate staff may conduct prenatal ultrasound after appropriate training and proctoring:
   - Performance of ultrasound — certified sonographers, radiologists and affiliate physicians with privileges in obstetrical ultrasound
   - Interpretation of ultrasound — radiologists or affiliate physicians with privileges in obstetrical ultrasound
2. See [redacted] above, for specifics about report.

IUC Insertion — Limited ultrasound may be used as an aid in inserting an IUC when palpation/confirmation of uterine position is difficult on bimanual exam.

IUC Localization — Limited ultrasound may be used as an aid in locating an IUC when the string is absent.
1. IUCs are echogenic. The presence of an intrauterine IUC on ultrasound excludes expulsion or translocation into the abdomen.
2. The absence of an intrauterine IUC could be due to expulsion or translocation. In this circumstance, further evaluation is required by a physician — either in the affiliate or by referral.
3. See [redacted] for more information on IUC localization.

Personnel and documentation
1. Only the following affiliate personnel may provide ultrasound for the purpose of IUC localization:
   - Performance of ultrasound — licensed health professional, certified sonographer, radiologist, or affiliate physician privileged in ultrasound for IUC localization
   - Interpretation of ultrasound — radiologist, affiliate physician privileged in ultrasound for IUC localization
     - When confirmation of an intrauterine IUC is made by ultrasound, interpretation may be done by clinician who is privileged in ultrasound interpretation for IUC localization.
2. See [redacted] above, for specifics about report.

Required Approvals — Only affiliates approved for Level II (Expanded Office) GYN and/or Level III (Expanded Surgical) GYN may provide on-site ultrasound for gynecologic conditions.

Referral — When a more comprehensive ultrasound is indicated, the client must be referred to an out-of affiliate radiology service for performance and interpretation of the ultrasound.

Transvaginal Probe — If possible, transvaginal probe is preferred for structures within the focal range of the vaginal probe. For structures outside of this range, a transabdominal
ultrasound is required.

Personnel and Documentation
1. Only the following affiliate personnel may provide gynecological ultrasound examinations:
   - Performance of ultrasound — affiliate-employed certified sonographers, affiliate-employed certified radiologists or affiliate physicians privileged in the performance of gynecologic ultrasound
   - Interpretation of ultrasound — Affiliate personnel interpreting and providing final reports for gynecologic ultrasound must be:
     - Affiliate-employed certified radiologists
     - Affiliate physicians with the following qualifications:
       - Completion of a United States OB/GYN residency which included at least 300 ultrasounds
       - Other physician with at least 16 hours of Cat I CME in basic and advanced ultrasound, and documentation of a minimum of 100 ultrasounds, at least half being supervised by a physician competent in ultrasound
       - Those physicians who in their practice of medicine have completed 16 hours of Category I CME in basic and advanced ultrasound and have performed and interpreted at least 300 pelvic ultrasounds.
2. See above, for specifics about the report.

In addition to those situations specified elsewhere in this section, referral out of the affiliate for ultrasound evaluation or other evaluation and management is required for:
1. poor visualization of anatomical structures with the affiliate ultrasound
2. suspected placenta accreta or percreta in second or third trimester
3. a visualized or suspected complex adnexal mass
4. known malignancy
5. suspected malignancy based on affiliate sonogram
This page has been left blank intentionally.
Ultrasound may be required as part of a variety of affiliate services. Service approval is not required.

Performance vs. Interpretation of Ultrasound
1. Performance of the ultrasound is the act of doing the examination — taking the measurements, creating a printed image, and reporting the findings for interpretation.
2. Interpretation of the ultrasound is reviewing the findings, providing an impression or conclusion, and approving and signing the final written report.

Client Viewing of Ultrasound Images — Any client who undergoes an ultrasound at the affiliate must be offered the opportunity to view the ultrasound image.
1. Clients who request a copy of the ultrasound image should be accommodated whenever possible.
2. See Documentation, below.

FYE — Practice Guidelines

In 2004 and 2007, the American Institute of Ultrasound in Medicine (AIUM), the American College of Radiology (ACR), and the American College of Obstetricians and Gynecologists (ACOG) published practice guidelines for the performance of pelvic and obstetric ultrasound, respectively. The types, indications and components of ultrasound as outlined in these guidelines is incorporated into this document.

DOES NOT PERFORM PELVIC ULTRASOUND EXCEPT FOR POST MEDICAL ABORTION FOLLOWUP

1. Indications – include but are not limited to
   a. Evaluation of Level I gynecological conditions including pelvic pain, abnormal uterine bleeding, amenorrhea
   b. Evaluation of Level II gynecological conditions such as structural abnormalities
   c. Evaluation and management of of Level III gynecological conditions
   d. IUC Localization
   e. Evaluation of postmenopausal bleeding
   f. Provision of basic infertility services
   g. Provision of expanded infertility services
2. Components – depending upon reason for ultrasound, the following structures should be evaluated as indicated
   a. Uterus

Revised 2012, Implemented 2012
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4. anatomic areas scanned
5. normal findings and/or abnormalities
6. diagnostic impression
7. specific findings related to the purpose of the exam (e.g., intrauterine gestation/size, number, IUC)
8. comparison with previous ultrasounds for the same condition, if applicable

Clients and Ultrasound Images — Documentation in the client record must include that the client was offered the opportunity to see her ultrasound, her response to the offer, and whether she was given a copy of the ultrasound image.

FYI — Options for viewing the ultrasound

Affiliates have shared that they most commonly offer women the option to view the ultrasound in one of two ways — a direct question to the client or indirectly as part of the client intake form. Either way is acceptable. Document that the option was offered, whether or not the client chose to view the image, and that it was shown to her (if applicable).

Client preferences:
Do you want to see the ultrasound? ____Yes ____No
Do you want to know if there is more than one pregnancy? ____Yes ____No

If the client indicates yes to either question, the record can simply have a checkbox:

_____ Client shown ultrasound image
_____ Client given a copy of the image
_____ Client informed of multiple pregnancies

Prior to the Performance of Ultrasound — The Request for Medical Services or the Request for Surgery or Other Special Services/Procedures must be signed or already present in the client’s record.

Limitations of the Ultrasound — The client must be informed of the limitations of the ultrasound being performed. For example, an ultrasound for pregnancy dating only would not be evaluating fetal anatomy:
1. Information may be given verbally.
2. It must be documented in the client’s medical record that the information was given.

Referral out of the affiliate for ultrasound evaluation or other evaluation and management is required for
1. when a more comprehensive ultrasound is indicated
Plan of Correction to Complaint

ID Prefix Tag: T2114

Statement of Deficiency

The MR for Patient A lacks complete information regarding an event that was [redacted] during an emergency, (see pertinent findings in T 2008)

Plan of Correction

Also, the US reports in Patients A's and other patient's lack complete information and legible signatures., (see the findings in tags T2008 and T2056)

Implementation and Monitoring

Managers to conduct Emergency drills and audit every 6 months with a report to the Committee

Please refer to T2008 and T2056

Please refer to T2008 and T2056

Americans United for Life
August 23, 2013

RE: Complaint #

Dear [Name],

On April 29, 2013 this office issued a Statement of Deficiencies in connection with the complaint referenced above. On May 10, 2013 the facility submitted a Plan of Correction (POC).

Review of the POC reveals it is partially acceptable, as noted on the enclosed form. Accordingly, a revised POC must be submitted within ten (10) business days from receipt of this letter to the following address: New York State Department of Health, [Address].

Should you have any questions, please contact me at [Phone Number].

Sincerely,

[Signature]
COMPLAINT STATEMENT OF DEFICIENCIES ISSUED ON APRIL 29, 2013
RESPONSE TO THE PLAN OF CORRECTION DATED MAY 10, 2013

Corrective action(s) are developed to fix/address the identified cause of the deficient practice cited and to prevent recurrence of that deficient practice.

Monitoring plans involve mechanisms or processes you will use to evaluate in a timely manner whether or not the corrective actions are effective, i.e., the plan must describe actions (steps) that will be taken by specified individuals (identified by position/title) soon after corrective actions are completed, and then periodically, to determine if they are working.

KEY:
ACOG = American College of Obstetricians and Gynecologists
ACR = American College of Radiology
AIUM = American Institute of Ultrasound in Medicine
US = Ultrasound
POC = Plan of Correction
P&P = Policy and Procedures

TAG # | CITATION | FINDING | COMMENTS/REQUIREMENTS
---|---|---|---
T 2008 | 751.2 ORGANIZATION AND ADMINISTRATION (b) Operator | PARTIALLY ACCEPTABLE | The revised POC must:

- include a revised P&P which addresses the following:
  - a requirement that US reports include all obtained during the procedure and, when repeat US is advised, a clear explanation of why the repeat US is necessary; and
  - a requirement that final reports in patients' medical records include an official interpretation by a physician.
COMPLAINT
STATEMENT OF DEFICIENCIES ISSUED ON APRIL 29, 2013
RESPONSE TO THE PLAN OF CORRECTION DATED MAY 10, 2013

COMMENTS/REQUIREMENTS

(NOTE: This is required by the nationally recognized AIUM in its Standards and Guidelines for the Accreditation of Ultrasound Practices, dated 11/5/11. In this document the AIUM specifically states, "The rendering of a final diagnosis of ultrasound studies represents the practice of medicine and, therefore, is the responsibility of the supervising physician.");

- include a written P&P describing requirements and process for training and credentialing sonographers;

- include a revised \[ \text{which includes provisions for recording the following information (as required by the ACR-ACOG – AIUM Practice Guideline for the Performance of Obstetrical Ultrasound, last revised 2007):} \]
<table>
<thead>
<tr>
<th>TAG #</th>
<th>CITATION</th>
<th>FINDING</th>
</tr>
</thead>
</table>
|       |          | - include description of the corrective action used to [
|       |          |         |
|       |          | include a revised |
|       |          | 1)       |
|       |          | 2)       |
|       |          | 3)       |
|       |          | - describe a specific frequency for audit/inspection of the emergency cart and contents (e.g., monthly and after each procedure), and indicate the inspections will be documented;
<p>|       |          | - indicate that P&amp;Ps no longer in effect will be removed from circulation and all staff will be informed when this happens; and |
|       |          | - indicate that staff competencies in the performance of checks will be evaluated during orientation and documented. |</p>
<table>
<thead>
<tr>
<th>TAG #</th>
<th>CITATION</th>
<th>FINDING</th>
<th>COMMENTS/REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2056</td>
<td>751.5 ORGANIZATION AND ADMINISTRATION (a)</td>
<td>PARTIALLY ACCEPTABLE</td>
<td>See Comments / requirements under Tag 2008 regarding US services, training, credentialing and reports.</td>
</tr>
</tbody>
</table>
| T 2114 | 751.7 ORGANIZATION AND ADMINISTRATION (d) | NOT ACCEPTABLE | The revised POC must:  
- describe how the facility will ensure all documentation in medical records is legible. |

For all tags referenced above, describe timely monitoring plans for evaluating the effectiveness of the corrective actions submitted. (Please see description of Monitoring Plans at the beginning of this document.)

Americans United for Life
September 6, 2013

Re: Complaint #

Dear [Name]

In response to your letter of August 23, 2013, we have made revisions to the plan of correction related to the subject complaint. You will find in the attached file the following changes in policies and procedures and forms. We also respectfully offer a response to the question you raised about which level of clinical staff can interpret gestational ultrasounds and the AIUM guidelines.

Tags 2008 and 2006:

1. We revised the [redacted]
2. We have submitted a [redacted]
3. We [redacted]
4. We [redacted]
5. We [redacted]
6. We specified the inspection and audit set-up for the emergency cart;
7. We reinforced the [redacted] and
8. We [redacted] related to [redacted]
Limited Obstetric Gestational Ultrasounds:

The following points support our interpretation of the guidance and privileging surrounding the practice of limited obstetric gestational ultrasounds used prior to and after abortion procedures. We believe we have been cited in error as the AIUM standards cited in the Statement of Deficiency are not generally accepted standards in the context of gestational ultrasounds.

We also reference several reputable sources, including but not limited to the AIUM Practice Guidelines in developing the approach on gestational ultrasound. The recommendations on gestational ultrasound reflect a more accurate and widely accepted standard on this specific issue and the approach accordingly. According to AIUM, "Practice Guidelines of the AIUM are intended to provide the medical ultrasound community with guidelines for the performance and recording of high-quality ultrasound examinations." The Practice Guidelines include the "AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations" which does not state who can and cannot interpret ultrasound. The "Standards and Guidelines for the Accreditation of Ultrasound Practices" which goes into some detail about who can interpret ultrasound, is not a practice guideline. It is the rules around which an Ultrasound Practice can become accredited by AIUM. Many office-based practices are not accredited by AIUM. These AIUM guidelines recognize that "deviations from the guideline will be needed in some cases depending on patient needs and available equipment." Moreover, an approach that differs from the guidelines, standing alone, does not necessarily imply the approach is below the standards of care.

We submit that the approach described above is an acceptable protocol. A review of the
The [inserted on the following page] states that physicians and clinicians can interpret ultrasound for the purpose of abortion. Only physicians may interpret prenatal ultrasound. We agree fully that advanced practice staff need appropriate training, proctoring, as well as privileging and we have clarified our policy and procedure related to training and privileging as noted above.

The [inserted] states:

- Licensed staff
  - May perform and/or interpret ultrasound examinations. See [inserted] below, for information on which licensed staff may perform and interpret ultrasound for specific services.
  - Must be granted clinical privileges to perform and/or interpret ultrasound. Clinical privileges should include separate categories for performing and interpreting each type of ultrasound listed.
<table>
<thead>
<tr>
<th>Type of Service</th>
<th>Personnel</th>
<th>Qualifications</th>
</tr>
</thead>
</table>
| Other Gynecologic Conditions (Levels 1, 2, 3) A-1 | certified sonographers  
certified radiologists  
affiliated physicians | certified radiologists  
affiliated physicians with the following qualifications  
- completion of a United States OB/GYN residency which included at least 300 ultrasounds OR  
- completion of at least 16 hours of Class 1 CME in basic and advanced ultrasound, and documentation of a minimum of 100 |
| Menopause                          | licensed health professional  
certified sonographer  
radiologist | radiologist  
affiliated physician |
| Infertility (Levels 1, 2)           |                                                    | When confirmation of an intrauterine IUC is made by ultrasound, interpretation may be done by clinician |
| IUC localization                   |                                                    |                                                                                |
| Abortion (Sections)                | non-licensed personnel  
licensed nurses  
clinicians  
certified sonographers  
physicians | clinicians  
physicians |
| Early Pregnancy Evaluation (        |                                                    |                                                                                |
| Prenatal Care                      | certified sonographers  
radiologists  
affiliated physicians | radiologists  
affiliated physicians |
Should you have any questions or comments on the material we have submitted please do not hesitate to contact me.
Plan of Correction in Response to Statement of Deficiencies Issued on August 23, 2013
Regarding Complaint: [Redacted]

ID PREFIX TAG: T 2008

Statement of Deficiency

- Requirement that US reports include all measurements
- Documentation of repeat US
- Interpretation of US images
- Training and Credentialing

Plan of Correction

- Refer to [Redacted] pages
- Refer to [Redacted] page
- AIUM provides guidelines that are not intended to establish legal standards of care. [Redacted] is not required to be AIUM accredited. [Redacted] is in compliance by adhering to the established policy for interpretation of US images. Refer to [Redacted] page
- Training of sonographers is stated in the [Redacted] policy revised to include credentialing of sonographers. Refer to [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Implementation and Monitoring

- [Redacted] has been following measurement guidelines per policy
- Revision to policy 9/13, Lead clinician and Medical Director will monitor repeat scans quarterly beginning October 2013
- In compliance
- Credentialing of sonogram privileges for providers is being presented and granted by the Board of Directors. In compliance. Will monitor as each new provider is granted privileges.
- In compliance
- Inform state of form changes 9/13.
- [Redacted] will monitor form
Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013

Regarding Complaint

ID PREFIX TAG: T 2008

Statement of Deficiency

Plan of Correction

quarterly beginning October 2013

Implementation and Monitoring

- [Redacted] 9/13, will monitor form quarterly beginning October 2013

- In Compliance

- [Redacted] to include facility identification 9/13, will monitor form beginning October 2013 quarterly

- [Redacted] to include how patient tolerated procedure 9/13, will monitor form quarterly beginning October 2013

- [Redacted] 9/13, will monitor transfer charts quarterly beginning October 2013

- Inform staff of form changes 9/13. Monitor the evaluation form for all occurrences. Conduct emergency drills biannually. Next drill due 10/13

Implementation and Monitoring

- [Redacted] revised. Refer to [Redacted]
- Counseling of physician provided by the Medical Director. Documentation submitted to DOH previously.
- Communication to the Medical Staff done 9/13

Americans United for Life
Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint [redacted]

ID PREFIX TAG: T 2008

Statement of Deficiencies
- [redacted]
- Archive [redacted]
- Orientation of staff

Plan of Correction
- Currently in compliance. Will monitor in December 2013
- Revised orientation checklists will be implemented 9/13

[Logo: Americans United for Life]
Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint [Redacted]

ID PREFIX TAG: T 2008
Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint:

ID PREFIX TAG: 2056

<table>
<thead>
<tr>
<th>Statement of Deficiency</th>
<th>Plan of Correction</th>
<th>Implementation and Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>• US services training, credentialing and reports</td>
<td>• Refer to Tag 2008</td>
<td>• Refer to Tag 2008</td>
</tr>
</tbody>
</table>

Americans United for Life
Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint [Redacted]

ID PREFIX TAG: 2056
Plan of Correction in response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint: [Redacted]

ID PREFIX TAG: 2114

<table>
<thead>
<tr>
<th>Statement of Deficiency</th>
<th>Plan of Correction</th>
<th>Implementation and Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Documentation of Medical Records is legible</td>
<td>• Implementation of Electronic Health Records has begun.</td>
<td>Will be in compliance after [Redacted] are on the new system 11/13</td>
</tr>
</tbody>
</table>
Plan of Correction in Response to Statement of Deficiencies issued on August 23, 2013
Regarding Complaint

ID PREFIX TAG: 2114
Received - thank you!

RESPONSES MUST BE SENT TO THIS E-MAIL ADDRESS ONLY.

Attached are the additional materials requested. Please confirm receipt.

Many thanks,
December 5, 2013

Dear [Name],

This note is to submit as requested the documentation related to Plan of Correction #2, Addendum #2. Including materials related to Tag # 2008 and [redacted] Article 28 survey.

Please do not hesitate to call me with any questions or comments on the materials submitted.

Sincerely,

[Signature]

[Logo] Americans United for Life
Document Index for POC #2, Addendum#2

1. Cover Letter

2. 

3. T2008 Monitoring plan revised to include more comprehensive monitoring

4. 

5. 

6. Plan of Correction for Infection Control Program: plan has been revised to include more comprehensive and intensive monitoring of program

7. 

8. 

9. 

Americans United for Life
January 13, 2014

RE: Complaint

Dear

On April 29, 2013 this office issued a Statement of Deficiencies in connection with the complaint referenced above. On May 10, 2013 the facility submitted a Plan of Correction (POC).

On August 23, 2013 this office responded that the POC was only partially acceptable. On September 6, 2013 the facility submitted a second POC. Addendum to the second POC were submitted on November 6, 2013, December 15, 2013, and January 3, 2014.

Review of the Second POC reveals it is acceptable, as noted on the enclosed form. Please continue implementation of the plan as this office will monitor compliance during future surveillance activities.

Should you have any questions, please contact me at

Sincerely,

[Redacted]

[Logo: Americans United for Life]

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twitter.com/HealthNYGov
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>T 2008</td>
<td>751.2 ORGANIZATION AND ADMINISTRATION (b) Operator</td>
<td>ACCEPTABLE</td>
<td></td>
</tr>
<tr>
<td>T 2056</td>
<td>751.5 ORGANIZATION AND ADMINISTRATION</td>
<td>ACCEPTABLE</td>
<td></td>
</tr>
<tr>
<td>T 2114</td>
<td>751.7 ORGANIZATION AND ADMINISTRATION</td>
<td>ACCEPTABLE</td>
<td></td>
</tr>
<tr>
<td>DATE</td>
<td>CONSEQUENCE</td>
<td>KEY ACTION/COMPLIANCE Goal</td>
<td>SPECIFIES</td>
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<td>12/2014</td>
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</tbody>
</table>

**Compliance Goal: 100%**

- **Director's Review:** 20 screening criteria will be sent to the Program Director for review.
- **Program/Instructor's Review:** 20 screening criteria will be sent to the Program Director for review. The Program Director will review any deviations from the required components with the screening criteria. The Program Director will receive any deviations from the required components with the screening criteria.

**Testing:**

- **Program Director:** Conducted the testing.
- **Instructor:** Conducted the testing.

**Program Components:**

- All required components are completed.
- All required components are completed.
- All required components are completed.
- All required components are completed.

**Training:**

- All required components are completed.
- All required components are completed.
- All required components are completed.
- All required components are completed.