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	22C0001041	A. BUILDING _____ B. WING _____	01/06/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	150 EMORY STREET ATTLEBORO, MA 02703

(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) COMPLETION DATE
Q 000	INITIAL COMMENTS An on-site Medicare Recertification survey was conducted at the Four Women Health Services on 1/5/16 and 1/6/16. The Condition(s) of: 1. Governing Body and Management (416.41) 2. Quality Assessment and Performance Improvement (416.43) 3. Pharmaceutical Services (416.48) were not met. The Standard(s)of: 1. Performance Improvement Projects (416.43) 2. Emergency Personnel (416.44) 3. Other Practitioners (416.45) 4. Administration of drugs (416.48) 5. Laboratory Services (416.49) 6. Infection Control Program (416.51) were not met. Please refer to the Conditions of Coverage for Ambulatory Surgery Centers at 42 CFR, 416.00	Q 000		
Q 040	GOVERNING BODY AND MANAGEMENT CFR(s): 416.41 The ASC must have a governing body that assumes full legal responsibility for determining, implementing,and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness	Q 040		2/1/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 01/25/2016

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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Q 040	Continued From page 1 plan. This CONDITION is not met as evidenced by: Based on observation, document review and staff interview, the Governing Body failed to assume full legal responsibility for determining, implementing and monitoring policies governing the Ambulatory Surgical Center's (ASC) total operation. The Governing Body failed to provide an effective, data driven Quality Assessment and Performance Improvement (QAPI) program, failed to provide oversight and direction to the ASC's pharmaceutical services to insure safe medication practices consistent with standards of practice, and failed to implement a formal infection control program. Findings include: 1. During an interview on 1/5/16 at 10:10 A.M., the Administrator/Nurse Practitioner said the ASC is owned by the Medical Director and she provides the oversight to insure that the day-to-day operational functioning of the ASC was consistent with facility policies. The ASC does surgical procedures 2 days a week and she sees patients one day a week. The Administrator/Nurse Practitioner said that in addition to providing patient care she performs the day to day functions of: - Human Resources; - Management of Nursing Services; - Management of contracted services; - Management of the physical plant; - Infection Control Program;	Q 040		

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Q 040	Continued From page 2 - Quality Assurance and Performance Improvement (QAPI); Review of personnel files had no evidence of ongoing training for staff and no evaluation of staff competencies for assigned tasks related to infection control and QA/PI activities. For 3 of 3 personnel files of the Medical Assistants (MA) reviewed, all 3 were performing venipuncture's. The facility /personal files had no policy and procedure for the MA's to perform this practice, no information included in the MA's job description for the task and no evaluation of there ability to perform the venipuncture. The MA staff were opening and compromising the integrity of multi-dose medication vials by removing the rubber septum and pouring the medication out of the vials. Additionally, the ASC ' s staff have not had a CPR mock code yearly as outlined in the facility ' s policies and procedures. Please refer to Q - 0080, Q-0180, Q-0106, Q - 0201 and Q - 0245. 2. The Governing Body failed to ensure that the Quality Assessment and Performance Improvement (QAPI) program is defined, implemented and maintained by the ASC. The Governing Body failed to ensure oversight and accountability for Pharmaceutical Services. Please refer to Q - 0080 and Q - 0081 3. The Governing body failed to provide oversight of the organization's infection control program to ensure that the Ambulatory Surgical Center had a	Q 040		

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Q 040	Continued From page 3 system to actively identify infections and had no supporting documentation that infections were tracked. During interview on 1/5/16 at 3:00 P.M. the Administrator/Nurse Practitioner, could offer no information or documentation of an on-going infection control program. Please refer to Q - 0245 4. The Governing Body failed to provide oversight and evaluate the quality of the clinical services provided by the Nurse Practitioner and Certified Registered Nurse Anesthesiologist staff.	Q 040		
Q 080	Q - 0123 QUALITY ASSESSMENT AND PERFORMANCE CFR(s): 416.43 The ASC must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement (QAPI) program. This CONDITION is not met as evidenced by: Based on facility document review, interviews and policy review, the Ambulatory Surgical Center (ASC) failed to implement and maintain an on-going data driven Quality Assessment and Performance Improvement (QAPI) program. Findings include: 1. Review of the ASC's Quality Assessment/Performance Improvement (QAPI) program indicated the ASC failed to collect and utilize data to measure all aspects of care provided by the ASC and use this data to assess quality, identify and address problems and	Q 080		2/9/16

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Q 080	Continued From page 4 improve performance. Review of the Quality Assurance/Patient Care Assessment Committee/Board (QAPI/CAC) meeting minutes, complication reports, incident reports and staff interviews, indicated that the Ambulatory Surgical Center (ASC) failed to consistently measure, analyze, and track quality indicators. The Administrator/Nurse Practitioner was identified as the Continuous Quality Improvement (CQI) Coordinator responsible for the monthly coordination and implementation of QA/PI activities. On 1/6/16 at 2:30 P.M., the Administrator/Nurse Practitioner said that the facility identified screening criteria of surgical occurrences as part of the Quality Assurance monitoring and evaluation process. The Administrator was unable to explain how the screening process resulted in data that could be used to evaluate care, identify facility problems and provide opportunities for improvement. The Administrator said the ASC had no infections but had no tracking of infections and not incorporated infections into the facility's QA/PI program scope and activities. Please refer to Q - 0083 and Q - 0245 2. Review of existing QAPI documentation and interview on 1/6/16 at 2:30 P.M. the Administrator indicated that a quality improvement project on "Patient Wait Times", "non-surgical time studies" and "patient satisfaction" had not had data analyzed since 3/31/15. There was no documentation that any of	Q 080		

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Q 080	Continued From page 5 the projects had been presented to the QA committee for oversight and action. There were no new performance improvement projects identified for 2015. Please refer to Q - 0083 3. Review of ASC meeting minutes, document review and staff interview, the Governing Body (GB) failed to provide oversight of the Quality Assessment and Performance Improvement Program (QAPI) and failed to ensure the effectiveness of the program was evaluated. Please refer to Q - 0083	Q 080		
Q 083	PERFORMANCE IMPROVEMENT PROJECTS CFR(s): 416.43(d) (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. (2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results This STANDARD is not met as evidenced by: Based on document review and staff interviews, the facility failed to ensure that the facility's Continuous Quality Improvement (CQI) program identified and implemented specific quality improvement projects on an annual basis. Findings include:	Q 083		1/20/16

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Q 083	Continued From page 6 1. Review of the CQI program data indicated that no quality improvement projects had been planned for or identified by the QA committee for calendar year 2015. Further review indicated that the QI projects of patient wait times, time study for non-surgical patients and patient satisfaction reports acted on in 2014 had not had it's data analyzed and not reported to the Governing Body in 2015. 2. According to the Administrator/Nurse Practitioner, at the Governing Body meetings of 5/29/15 and 9/22/15, they also have the QAPI meetings. A review of both the 5/29/15 and the 9/22/15 Goverening Body minutes/QAPI minutes, indicated there was no information listed for the QAPI program specific improvement projects. 3. On 1/5/16 at 9:00 A.M., the NP said there were no systems in place to monitor sharps injuries (needle sticks, breaks in the skin by a sharp object). Therefore, there were no results to report to the QI Committee. The facility policy indicated that a sharps injury log would be in place and it had not been implemented. In 2015 there were 3 sharps injuries that had occurred and the ASC did not track and trend these injuries.	Q 083		
Q 106	EMERGENCY PERSONNEL CFR(s): 416.44(d) Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.	Q 106		1/23/16

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Q 106	Continued From page 7 This STANDARD is not met as evidenced by: Based on staff interview and documentation, the Ambulatory Surgical Center (ASC) failed to follow their policy and procedure for having annual Cardiopulmonary Resuscitation drills. Findings included: A review of the Cardiopulmonary Resuscitation (CPR) Mock Drill policy, last approved 12/2015, indicated that to ensure that the staff are trained and respond appropriately in case of emergency CPR/mock drills are conducted yearly. The ASC documentation indicated the last CPR mock drill was conducted 8/14/14 and there was no documentation of having one in 2015. During interview on 1/6/16 at 2:30 P.M., the Administrator/Nurse Practitioner said there was no CPR drill conducted in 2015.	Q 106		
Q 123	OTHER PRACTITIONERS CFR(s): 416.45(c) If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. This STANDARD is not met as evidenced by: Based on staff interview and review of the personal files for the Nurse Practioner (NP) and the Certified Registered Nurse Anesthetist (CRNA) the Ambulatory Surgical Center(ASC) failed to establish procedures for the oversight and	Q 123		1/20/16

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Q 123	Continued From page 8 evaluation of the Practioner in 1 of 1 NP file and 2 of 2 CRNA's file. Findings include: Review of the personal files on 1/6/16 at 10:00 A. M. indicated that there was no documentation of oversight/evaluation of the physician extenders according to their scope of practice and as required by law. When a ASC uses a licensed practioner to provide patient care, other than nursing care, the ASC's governing body must approve written policies and procedures that establish a system for overseeing and evaluation the quality of the clinical services provided by other practioner's. The ASC's policies must address the specific type of clinical activities that each class of practioner, e.g. NP's, Physician's Assistants or CRNA, will be eligible to perform. The ASC may not permit performance of any activities that are outside the licensed practioner's permitted scope of practice under applicable State Las. On 1/6/16 at 2:45 P.M. the NP, the ASC's center administrator, said that the oversight is provided by the Medical Director, however there was no documentation to support this.	Q 123		
Q 180	PHARMACEUTICAL SERVICES CFR(s): 416.48 The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible	Q 180		1/20/16

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Q 180	Continued From page 9 for pharmaceutical services. This CONDITION is not met as evidenced by: Based on observation and staff interviews the Ambulatory Surgery Center (ASC) failed to ensure that drugs and biological's were provided in a safe and effective manner, in accordance with accepted professional practice. Findings include: 1. During initial tour at 8:30 A.M. on 1/5/16 with the Medical Assistant, the Surveyors noted expired medications, medications not being dated when opened as required by the ASC' policy when using multiply doses vials and expired anesthesia equipment in Operating Room (OR) #2 and in the stock room. Please refer to Q-181. On 1/5/16 at 8:30 A.M., MA #1 was explaining to the Surveyors the process for preparing the OR's for the procedure that included the local anesthetic, Lidocaine. The explanation further went to explain that the vial of Lidocaine was opened by removing the metal ring around the top of the vial and removing the rubber stopper. The multi-dose vial is manufactured to be accessed with a sterile needle and sterile syringe, This practice compromises the integrity of the multi-dose vial . Please refer to Q-181.	Q 180		
Q 181	ADMINISTRATION OF DRUGS CFR(s): 416.48(a)	Q 181		1/20/16

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Q 181	Continued From page 10 Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observation and staff interviews, the Ambulatory Surgery Center (ASC) failed to dispose of expired medications and anesthesia equipment in a timely manner and failed to date multi-dose vials (a vial of medication that can be used for several patients) when opened according to the ASC"s policy. Findings include: 1. During initial tour of the ASC at 8:30 A.M. on 1/5/16 with the Medical Assistant (MA) #1, the Surveyors noted expired medications, medications not being dated when opened as required by the ASC's policy when using multiple doses vials, potentially contaminating the vials contents by removing the metal ring and the vial's rubber stopper and expired anesthesia equipment in Operating Room (OR) #2. and the stock room. While performing the initial environmental tour on 1/5/16 at 8:30 A.M. with MA#1, it was observed that there were numerous vials of medication that were expired. These medications were kept in a draw in OR#2. The following medications had expired: a. 4 vials of single use vials of Rocuronium Bromide (provides skeletal muscle relaxation	Q 181		

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Q 181	Continued From page 11 during surgery) with an expiration date of 11/2015 b. 4 ampule's of single use vials of Methogen (used to prevent/control post partum hemorrhage) with 4 ampule's having having an expiration date of 11/2015. c. One liter Inter venous (IV) of Normal Saline with an expiration date of 11/2015. The expired surgical/anesthesia equipment observed is as follows: a. Single use Endotracheal Tubes (a flexible plastic tube that is put into the mouth and then down into the trachea airway. The purpose of using an enforceable tube is to ventilate the lungs). Three ET tubes had expirations dates of 10/28/13, 3/28/15 and 3/28/12. b. A shiley tracheal tube (a tube placed through an opening in the neck to provide an airway), that had an expiration date 4/20/2010. OR#1 was then toured with MA#1 and it was observed that the following had expired: a. An ET tube with an expiration date of 11/28/14. b. A trachea tube with an expiration date of 1/2003. c. 2 IV tubing sets with an expiration dates of 7/2015. On 1/5/15 at 9:30 A.M., MA#1 said that the	Q 181		

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Q 181	Continued From page 12 anesthesiologist is responsible for checking expiration dates. The stock room/supply room was then toured with MA#1 and it was observed that a Foley catheter (a tube inserted into the bladder to drain urine) had an expiration date of 7/2015. 2. During the initial tour is was also observed that in OR#2 there was an open bottle of Lidocaine (a medication used for the purpose, in this ASC, to numb the cervix) with no date as to when is had been opened, and an IV setup of Lactated Ringers solution with no date and time on the set. The last date that any type of procedure was performed in OR#2 was on 1/2/16., At this time, 1/5/15 at 9:30 A.M., is was also observed that the metal ring on the vial of Lidocaine had been removed. The MA #1 said that the procedure is to take off the metal ring off the vial, remove the rubber septum and pour a certain amount for the surgeon who is performing the surgery. The principles for all all vial types is: a). Disinfect the vial's septum before piercing, 1. The vial cap does not ensure the vial septum is sterile 2. Use at least 70% isopropyl alcohol swab. 3. Use friction (i.e. scrub the hub) 4. The septum should be visibly wet, than allow to air dry for 10 seconds before piercing. b). Do not leave needles or other objects in the vial between use as this may contaminate the vials contents. On tour in the OR suite on 1/6/16 at 11:45 A.M.,	Q 181		

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Q 181	Continued From page 13 the NP/facility administrator again told the Surveyor that the bottles of Lidocaine were opened with a can opener. The NP then indicated that the door jam could also be used and proceeded to open a bottle of Lidocaine in the door jam of the ASC's narcotic storage area to remove the metal ring. On 1/6/15 at 12:30 P.M., the MA#1 performed a demonstration of setting up the surgical field and the procedure for pouring the Lidocaine into a surgical cup for the surgeons use. MA#1 again told the Surveyors that the metal ring around the vial was removed. On 1/6/16 at 2:30 P.M., the NP said that the ASC did not have a policy for this procedure and the metal ring should not be removed, as it could comprise the vial. The ASC's policy for use of Multi-dose vials did not address the removing of the metal ring.	Q 181		
Q 201	LABORATORY SERVICES CFR(s): 416.49(a) If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of Part 493 of this chapter. This STANDARD is not met as evidenced by:	Q 201		1/20/16

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q 201	Continued From page 14 Based on staff interviews, reviews of personal records and policy and procedures, the Ambulatory Surgical Center (ASC) failed to ensure that for 3 of 3 Medical Assistants (MA) performing phlebotomy services of venipuncture were trained and competent to perform the blood draws. Findings include: During the initial tour of the ASC on 1/5/16 from 8:30 A.M. - 10:00 A.M., Medical Assistant #1 provided the Survey team with a tour of the facility. The MA pointed out that all patients are brought to the patient changing area and the survey team observed phlebotomy supplies in the room. The MA said that the ASC started in 7/2015 with a new machine, the Hemacue HGB (hemaglobin), that tests patients Rh (Rhesus factor) status and requires the patients blood in test tubes to determine the patient's Rh typing. (positive or negative). A review of the ASC's Venipuncture policy for blood collection, had no information designating this task to the Medical Assistants. Review of 3 of 3 personal files for the Medical Assistants (MA), indicated there was no information that the MAs performed this blood draw task and there was no information of the ASC having evaluated the MAs' ability to perform venipunctures. During interview on 1/6/16 at 2:30 P.M., the Administrator/Nurse Practitioner said there was no information in the ASC policy that designated venipucture to be performed by MAs and no	Q 201		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	22C0001041	A. BUILDING _____ B. WING _____	01/06/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	150 EMORY STREET ATTLEBORO, MA 02703

(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) COMPLETION DATE
Q 201	Continued From page 15 evaluation of the MAs' competency to perform the blood draws.	Q 201		
Q 245	INFECTION CONTROL PROGRAM CFR(s): 416.51(b)(3) The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement. This STANDARD is not met as evidenced by: Based on staff interview, the Ambulatory Surgical Center (ASC) failed to have a plan of action for preventing, identifying, and managing infections and communicable disease. The ASC had no active surveillance and no plan to identify infection control issues. Findings include: The ASC could not provide documentation or describe any plan of action of how the infection control program would take preventive or corrective measures to improve the ASC's infection control outcomes. There was no infection control policy to review for active surveillance and no plan of identify infection control issues. Interview on 1/6/16 at 3:00 P.M. the Nurse Administrator said, there was no system and no tracking activity for infections.	Q 245		1/20/16

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	44H1	A. BUILDING: _____ B. WING _____	07/31/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	150 EMORY STREET GROUND FLOOR ATTLEBORO, MA 02703

(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
C 000	INITIAL COMMENTS An onsite licensure renewal survey was conducted of the Clinic on 7/31/19 for the provision of medical and surgical services. Deficiencies were cited.	C 000		
C 380	140.301(B)(5) Administrative Records - Policies & Procedure (B) Administrative records shall include: (5) Written policies and procedures designed to safeguard the health and safety of patients and staff. These policies and procedures shall be reviewed and updated annually. This ELEMENT is not met as evidenced by: Based on documentation review and interview, the Clinic failed to review their policies and procedures on an annual basis. Findings include: Surveyor's review of the Clinic's policy and procedure binders found that the policies and procedures were last reviewed on 2/21/17. During an interview on 7/31/19 at 11:52 A.M., the Clinic Manager said that the policies and procedures had not been reviewed on an annual basis.	C 380		
C1320	140.347(E) Clinics Without Pharmacies - Outdated Drugs	C1320		

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	44H1	A. BUILDING: _____ B. WING _____	07/31/2019

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C1320	Continued From page 1 Outdated drugs shall be eliminated from the clinic's stock in accordance with clinic policies. All drugs shall be destroyed in accordance with applicable state and federal laws. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to date a multiple dose bottle of medication when it was opened, to ensure product stability. Findings include: During the inspection of the medication closet on 7/31/19 at 12:06 P.M., accompanied by the Clinic Administrator, the Surveyor observed an open bottle of lidocaine (an anesthetic) which was not dated when opened. The Clinic Administrator said that the bottle was likely opened last week, and that it should have been dated when it was opened. *The Centers for Disease Control and Prevention (CDC) recommends that multi-dose vials be discarded 28 days after being opened to prevent contamination.	C1320		
C3430	140.1201(D) End of Life - Policies Each clinic shall have a policy to guide its attending health care practitioners for identifying appropriate patients and ensuring that they receive an informational pamphlet. Such policies shall be made available to the	C3430		

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	44H1	A. BUILDING: _____ B. WING _____	07/31/2019

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C3430	Continued From page 2 Department upon request. This REQUIREMENT is not met as evidenced by: Based on document review and staff interview, the Clinic failed to develop a policy to guide its attending health care practitioners in identifying appropriate patients for palliative and end of life care and ensuring that they receive an informational pamphlet. Findings include: Surveyor's review of the Clinic's policies and procedure binders did not find a policy or procedure regarding palliative or end of life care. During an interview on 7/31/19 at 11:50 A.M., the Clinic Manager said that she could not locate such a policy or informational pamphlet.	C3430		

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	22C0001041	A. BUILDING **01 - ASC CENTER (01)** B. WING _____	**01/12/2016**

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	**150 EMORY STREET ATTLEBORO, MA 02703**

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K 000	INITIAL COMMENTS LIFE SAFETY CODE 42 CFR 416.44(b) The facility must meet the applicable provisions of the 2000 edition of the "LIFE SAFETY CODE" (LSC) of the "National Fire Protection Association" (NFPA) #101 for an Existing Ambulatory Health Care Occupancy surveyed under chapter 21 . Form CMS-2786U was completed.	K 000		
K 020	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) Vertical openings such as stairways, elevator shaftways, escalators, and building service shaftways are enclosed in accordance with section 8.2.5. 8.2.5.2, 38.3.1, 39.3.1 This STANDARD is not met as evidenced by: Based on observations and confirmed by staff, the facility failed to ensure stairwells are properly maintained. Section 21.3.1 states protection of vertical openings shall comply with section 39.3.1. Section 39.3.1 states any vertical opening shall be enclosed or protected in accordance with section 8.2.5. Section 8.2.5.1 states every floor that separates stories in a building shall be constructed as a smoke barrier to provide a basic degree of compartmentation. Section 8.2.5.2 states openings through floors, such as stairways, hoistways for elevators, dumbwaiters, and inclined and vertical conveyors; shaftways used for light, ventilation,	K 020		2/26/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 01/30/2016

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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K 020	Continued From page 1 or building services; or expansion joints and seismic joints used to allow structural movements shall be enclosed with fire barrier walls. Such enclosures shall be continuous from floor to floor or floor to roof. Openings shall be protected as appropriate for the fire resistance rating of the barrier. THE FINDINGS INCLUDE: During the morning hours of 1/12/16 at approximately 10:30 A.M., the rear stairwell door was tested for proper operation. Although the door opens and closes as required, the door is lacking a self closing device as required. As a result, the facility failed to comply with Section 21.3.1. This was acknowledged by the Medical Assistant during the exit interview process.	K 020		
K 029	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) Hazardous areas separated from other parts of the building by fire barriers have at least one hour fire resistance rating or such areas are enclosed with partitions and doors and the area is provided with an automatic sprinkler system. High hazard areas are provided with both fire barriers and sprinkler systems 38.3.2, 39.3.2 This STANDARD is not met as evidenced by: Based on observations and confirmed by staff, the facility failed to ensure that hazardous areas are separated and maintained as required. Section 21.3.2 states protection from hazards	K 029		2/26/16

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K 029	Continued From page 2 shall comply with section 39.3.2. Section 39.3.2. states hazardous areas including, but not limited to, areas used for general storage, boiler or furnace rooms, and maintenance shops that include woodworking and painting areas shall be protected in accordance with Section 8.4. Section 8.4.1.1 states protection from any area having a degree of hazard greater than that normal to the general occupancy of the building or structure shall be provided by one of the following means: (1) Enclose the area with a fire barrier without windows that has a 1-hour fire resistance rating in accordance with Section 8.2. (2) Protect the area with automatic extinguishing systems in accordance with Section 9.7. (3) Apply both 8.4.1.1(1) and (2) where the hazard is severe or where otherwise specified by Chapters 12 through 42. THE FINDINGS INCLUDE: During the morning hours of 1/12/16 at approximately 11:30 A.M., the following items were observed regarding hazardous locations: 1) The two doors to the furnace room were observed to be of non-rated hollow core construction. It was also observed that the doors are not equipped with any self closing device as required. 2) Numerous unsealed penetrations were observed in the walls to the boiler room, these include but are not limited to the following locations: a) Two transfer grills in the wall adjacent to the	K 029		

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K 029	Continued From page 3 medical records room, b) Two old exhaust ducts in the wall adjacent to the old operating room, c) An approximate 8" x 18" non sealed penetration in the wall adjacent to the office area. NOTE: The facility in non-sprinklered and requires a 1-hour separation of hazardous areas. As a result, the facility failed to comply with Section 21.3.2. This was acknowledged by the Medical Assistant during the exit interview process.	K 029		
K 046	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) Emergency illumination is provided in accordance with section 7.9. 20.2.9.1, 21.2.9.1 This STANDARD is not met as evidenced by: Based on observations and confirmed by staff, the facility failed to ensure that emergency lighting is tested as required. Section 21.2.9.1 states emergency lighting shall be provided in accordance with Section 7.9. Section 7.9.3 states a functional test shall be conducted on every required emergency lighting system at 30-day intervals for not less than 30 seconds. An annual test shall be conducted on every required battery-powered emergency lighting system for not less than 11/2 hours. Equipment shall be fully operational for the duration of the test. Written records of visual inspections and tests shall be kept by the owner for inspection by the authority having jurisdiction.	K 046		2/1/16

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K 046	Continued From page 4 THE FINDING INCLUDE: While reviewing documentation during the morning of 1/12/16 at approximately 9:00 A.M., it was observed that the testing of the emergency lighting is not documented as required. The facility has no records indicating that the emergency lighting is tested monthly or annually as required. It was stated by facility staff that the testing is performed but not documented. As a result, the facility failed to comply with Section 21.2.9.1. This was acknowledged by the Medical Assistant during the exit interview process.	K 046		
K 047	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) Exits and ways of travel thereto are marked in accordance with section 7.10. 20.2.10, 21.2.10 This STANDARD is not met as evidenced by: Based on observations and confirmed by staff, the facility failed to ensure that emergency exit routes are marked as required. Section 21.2.5 states arrangement of means of egress shall comply with section 39.2.5. Section 39.2.5 states means of egress shall be arranged in accordance with Section 7.5. Section 7.5.1.7 states exit access from rooms or spaces shall be permitted to be through adjoining or intervening rooms or areas, provided that such adjoining rooms are accessory to the area served. Foyers, lobbies, and reception rooms constructed as required for corridors shall not be construed as intervening rooms. Exit access shall	K 047		2/26/16

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K 047	Continued From page 5 be arranged so that it is not necessary to pass through any area identified under Protection from Hazards in Chapters 11 through 42. Section 39.3.2.1 states hazardous areas including, but not limited to, areas used for general storage, boiler or furnace rooms, and maintenance shops that include woodworking and painting areas shall be protected in accordance with Section 8.4. THE FINDINGS INCLUDE: During the morning hours of 1/12/16 at 10:00 A.M., an exit sign was observed above the furnace room door. Although the furnace room has a door leading to the exterior of the facility, exiting through a hazardous area is not permitted per 7.5.1.7. Note: The facility has the required amount of egress routes without utilizing the designated exit through the furnace room. As a result, the facility failed to comply with Section 21.2.5. This was acknowledged by the Medical Assistant during the exit interview process.	K 047		
K 050	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) Fire drills are held at unexpected times under varying conditions, at least quarterly on each shift. The staff is familiar with procedures and is aware that drills are part of established routine. 20.7.1.2, 21.7.1.2	K 050		2/1/16

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K 050	Continued From page 6 This STANDARD is not met as evidenced by: Based on observation, record review, and confirmed by staff, the facility failed to ensure that fire drills are conducted as required. Section 21.7.1.2 states fire drills in ambulatory health care facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions. Drills shall be conducted quarterly on each shift to familiarize facility personnel (nurses, interns, maintenance engineers, and administrative staff) with the signals and emergency action required under varied conditions. When drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms. THE FINDINGS INCLUDE: During the morning hours of 1/12/16 at approximately 8:30 A.M. while reviewing the provided fire drills, it was observed that drills are not performed as required. The documented drills are dated, 12/9/15; 9/5/15; 2/20/15 and 11/15/14. A time period of over 6-1/2 months passed between the February and September fire drills, exceeding the 3-month allowance. As a result, the facility failed to comply with section 21.7.1.2. This was acknowledged by the Medical Assistant during the exit interview process.	K 050		
K 051	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) A manual fire alarm system, not a pre-signal type, is provided to automatically warn the building	K 051		2/1/16

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K 051	Continued From page 7 occupants. Fire alarm system has initiation notification and control function. The fire alarm system is arranged to automatically transmit an alarm to summon the fire department. 20.3.4.1, 21.3.4.1 This STANDARD is not met as evidenced by: Based on observations, record review, and confirmed by staff, the facility failed to ensure the fire alarm system is tested and maintained as required. Section 21.3.4.1 states ambulatory health care facilities shall be provided with fire alarm systems in accordance with Section 9.6, except as modified by 21.3.4.2 through 21.3.4.5. Section 9.6.1.4 states a fire alarm system required for life safety shall be installed, tested, and maintained in accordance with the applicable requirements of NFPA 70, National Electrical Code, and NFPA 72, National Fire Alarm Code, unless an existing installation, which shall be permitted to be continued in use, subject to the approval of the authority having jurisdiction. NFPA 72. Table 7-3.2 #20 states Off-Premises Transmission Equipment shall be tested on a quarterly basis. Section 7.3.2 and Table 7.3.2 require systems with sealed batteries to have the battery charger tested annually, replace the battery every 4 years, to conduct a 30 minute battery discharge test annually, and to conduct a load voltage test semi-annually. Section 7-3.2.1 states smoke detector sensitivity shall be checked within 1 year after installation and every alternate year thereafter. After the second required calibration test, if sensitivity tests indicate that the detector has remained within its listed and marked sensitivity range (or 4	K 051		

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K 051	Continued From page 8 percent obscuration light gray smoke, if not marked), the length of time between calibration tests shall be permitted to be extended to a maximum of 5 years. If the frequency is extended, records of detector-caused nuisance alarms and subsequent trends of these alarms shall be maintained. In zones or in areas where nuisance alarms show any increase over the previous year, calibration tests shall be performed. Section 21.3.4.3 states occupant notification shall be accomplished automatically, without delay, upon operation of any fire alarm activating device by means of an internal audible alarm in accordance with 9.6.3. Section 9.6.3 notification shall be provided by audible and visible signals in accordance with 9.6.3.3 through 9.6.3.12. Section 9.6.3.7 states the general evacuation alarm signal shall operate throughout the entire building. THE FINDINGS INCLUDE: During the morning hours of 1/12/16 while reviewing the provided inspection reports dated 5/15/15 and 7/24/14, the following items were observed regarding testing and installation of the fire alarm system: 1) The off-premise transmission test is not performed quarterly as the system in inspected/tested on a quarterly basis. 2) There is no line item on the inspection reports documenting the annual testing of the battery charger is performed. 3) There is no line item on the inspection reports documenting the batteries have been replaced	K 051		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	**150 EMORY STREET ATTLEBORO, MA 02703**

(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) COMPLETION DATE
K 051	Continued From page 9 during the past 4-year period. 4) There is no line item on the inspection reports documenting the 30-minute annual discharge test of the batteries has been performed. 5) There is no line item on the inspection reports documenting the semi-annual load voltage battery testing has been performed. 6) There is no line item on the inspection reports documenting the smoke detectors have had a sensitivity test performed during the past 5-year period. 7) There are no audio/visual alarm devices located on the administrative side of the smoke barrier wall. This area houses both office space as well as patient counseling rooms. As a result, the facility failed to comply with Section 21.3.4.1. This was acknowledged by the Medical Assistant during the exit interview process.	K 051		
K 115	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) Ambulatory health care facilities are divided into at least two smoke compartments with smoke barriers having at least 1 hour fire resistance rating. Doors in smoke barriers are equipped with positive latcher. Doors are constructed of not less than 1¾ inch thick solid bonded core wood or equivalent. Vision panels are provided and are of fixed wire glass limited to 1,296 sq. inch per panel. 20.3.7.1, 20.3.7.2, 20.3.7.3, 21.3.7.1, 21.3.7.2, 21.3.7.3 This STANDARD is not met as evidenced by: Based on observations and confirmed by staff,	K 115		2/26/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	22C0001041	A. BUILDING **01 - ASC CENTER (01)** B. WING _____	**01/12/2016**

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	**150 EMORY STREET ATTLEBORO, MA 02703**

(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) COMPLETION DATE
K 115	Continued From page 10 the facility failed to ensure that smoke barrier walls and doors are properly maintained. Section 21.3.7.2 states the ambulatory health care facility shall be divided into not less than two smoke compartments. Section 21.3.7.4 states vision panels in the smoke barrier shall be of fixed fire window assemblies in accordance with 8.2.3.2.2. Section 21.3.7.6 states doors in smoke barriers shall be not less than 13/4-in. (4.4-cm) thick, solid-bonded wood core or the equivalent and shall be self-closing. A vision panel shall be required. THE FINDINGS INCLUDE: During the morning hours of 1/12/16 at approximately 11:45 A.M. while performing the facility tour, the following items were observed regarding smoke barrier walls and doors: 1) The smoke barrier door by the front entrance is not equipped with a self closing device. 2) The smoke barrier door by the rear of the waiting room is not equipped with a self closing device. In addition, this door is not equipped with a vision panel as required. 3) Each of the two smoke barrier doors have unsealed voids around the entire door perimeter where the drywall meets the original block walls. 4) The piping penetrating the smoke barrier wall by the front entrance has numerous unsealed penetrations. As a result, the facility failed to comply with Section 21.3.7.2. This was acknowledged by the Medical Assistant	K 115		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	22C0001041	A. BUILDING **01 - ASC CENTER (01)** B. WING _____	**01/12/2016**

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	**150 EMORY STREET ATTLEBORO, MA 02703**

(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) COMPLETION DATE
K 115	Continued From page 11 during the exit interview process.	K 115		
K 144	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) Generators are inspected weekly and exercised under load for 30 minutes per month in accordance with NFPA 99. 3.4.4.1, NFPA 110, 8.4.2 This STANDARD is not met as evidenced by: Based on observation, record review, and confirmed by staff, the facility failed to ensure that the emergency generator is maintained and tested as required. NFPA 110 section 6-4.1 states level 1 and level 2 Emergency Power Supply Systems (EPSSs), including all appurtenant components, shall be inspected weekly and shall be exercised under load at least monthly. NFPA 99 3-4.4.1.1 states generator sets shall be tested twelve (12) times a year with testing intervals not less than 20 days or exceeding 40 days. NFPA 110 section 6-4.2 states generator sets in Level 1 and Level 2 service shall be exercised at least once monthly, for a minimum of 30 minutes, using one of the following methods: (a) Under operating temperature conditions or at not less than 30 percent of the EPS nameplate rating (b) Loading that maintains the minimum exhaust gas temperatures as recommended by the manufacturer The date and time of day for required testing shall be decided by the owner, based on facility operations. Section 6-4.3 states load tests of generator sets shall include complete cold starts.	K 144		2/1/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	22C0001041	A. BUILDING **01 - ASC CENTER (01)** B. WING _____	**01/12/2016**

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	**150 EMORY STREET ATTLEBORO, MA 02703**

(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) COMPLETION DATE
K 144	Continued From page 12 THE FINDINGS INCLUDE: During the morning hours of 1/12/16 at approximately 9:30 A.M., it was observed that monthly load testing of the emergency generator is not performed as required. There is no documentation available to substantiate that testing was performed during the following months: August 2015; July 2015; March 2015; February 2015; January 2015; and December 2014. In addition to not performing monthly load tests, there is no documentation to substantiate that the generator is inspected on a weekly basis as required. As a result, the facility failed to comply with NFPA 110 section 6-4.2 for both monthly and weekly testing. This was acknowledged by the Medical Assistant during the exit interview process.	K 144		
K 211	LIFE SAFETY CODE STANDARD CFR(s): 416.44(b)(1) o Where Alcohol Based Hand Rub (ABHR) dispensers are installed in a corridor, the corridor is at least 6 feet wide o The maximum individual fluid dispenser capacity shall be 1.2 liters (2 liters in suites of rooms) o The dispensers have a minimum spacing of 4 ft from each other o Not more than 10 gallons are used in a single smoke compartment outside a storage cabinet.	K 211		2/26/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	22C0001041	A. BUILDING **01 - ASC CENTER (01)** B. WING _____	**01/12/2016**

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FOUR WOMEN	**150 EMORY STREET ATTLEBORO, MA 02703**

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K 211	Continued From page 13 o Dispensers are not installed over or adjacent to an ignition source. o If the floor is carpeted, the building is fully sprinklered. 19.3.2.7, CFR 403.744, 418.100, 460.72, 482.41, 483.70, 483.623, 485.623 This STANDARD is not met as evidenced by: Based on observations and confirmed by staff, the facility failed to ensure that alcohol based hand rub (ABHR) dispensers are installed as required. THE FINDINGS INCLUDE: During the morning hours of 1/12/16 at approximately 11:30 A.M., an ABHR was observed in the corridor by the patient counseling office. This area is equipped with carpeted floors and the facility is not protected by an automatic sprinkler system. This was acknowledged by the Medical Assistant during the exit interview process.	K 211		

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MA DPH/Division of Health Care Facility Licensure

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4WSC	A. BUILDING: _____ B. WING _____	05/06/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HEALTHQUARTERS, INC	**100 CUMMINGS CENTER, SUITE 131-Q BEVERLY, MA 01915**

(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
C 000	INITIAL COMMENTS An onsite was conducted on May 6, 2015, for the relocation of the parent clinic from 900 Cummings Center, Suite 126-R Beverly, to 100 Cummings Center Suite 131-Q, Beverly. for the medical services to the license: Parent: Health Quarters 100 Cummings Center, Suite 131-Q Beverly, MA 01915 Satellite: Health Quarters 101 Amesbury Street Lawrence, MA 01840 Satellite: Health Quarters 215 Summer Street Haverhill, MA 01830 Services: medical The clinic was not in compliance with applicable clinic licensure requirements.	C 000		
C 056	140.105(A) - (C) Transfer of Ownership & Change in Location Transfer of Ownership and Change in Location (A) The Department shall be notified immediately in writing of any proposed change in name or location of a facility. A license shall not be transferred from one person or entity to	C 056		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4WSC	A. BUILDING: _____ B. WING _____	05/06/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HEALTHQUARTERS, INC	100 CUMMINGS CENTER, SUITE 131-Q BEVERLY, MA 01915

(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
C 056	Continued From page 1 another or from one location to another. (B) The proposed licensee shall submit a Notice of Intent to acquire a clinic to the Department at least 30 calendar days in advance of any transfer of ownership. (C) Any person applying for a license as a result of any transfer of ownership shall file an application for licensure within 48 hours of the transfer or such longer period in advance as the Commissioner shall prescribe. If the Notice of Intent was not timely filed, at the discretion of the Commissioner, an application received as a result of a transfer of ownership will not be considered as filed for 30 calendar days, or such longer period as the Commissioner shall designate, after such application is received. This ELEMENT is not met as evidenced by: Based on documentation review and staff interview, the clinic failed to notify the Department before relocating from one location to another. Findings include: On 5/6/15, review of a letter, dated 3/3/15, to the Department from the clinic indicated that on 2/5/15, the clinic moved from 900 Cummings Center, Suite 126-R, Beverly to 100 Cummings Center, Suite 131-R, Beverly. The letter was sent to the Department 27 days after the clinic relocated to another location. On 5/6/15 at 10 :30 A.M., the Director said the clinic had to relocate to another building in a	C 056		

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MA DPH/Division of Health Care Facility Licensure

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4WSC	A. BUILDING: _____ B. WING _____	05/06/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HEALTHQUARTERS, INC	**100 CUMMINGS CENTER, SUITE 131-Q BEVERLY, MA 01915**

(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
C 056	Continued From page 2 short period of time. During the last week in 01/2015, the building's landlord for 900 Cummings Center had requested that the clinic vacate the building as soon as possible. The Director said she notified the Department after the clinic relocated to another location.	C 056		

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MA DPH/Division of Health Care Facility Licensure

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4174	A. BUILDING: _____ B. WING _____	07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	1055 COMMONWEALTH AVENUE BOSTON, MA 02215

(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
C 000	INITIAL COMMENTS An onsite licensure renewal survey was conducted of the Clinic on 7/3/19 for the provision of medical and surgical services. Onsite licensure renewal surveys were conducted for the following satellite clinics: 7/3/19 Planned Parenthood League of Central MA Center 470 Pleasant Street Worcester, MA 01609 services: medical and surgical 7/10/19 Planned Parenthood League of MA- Marlborough 91 Main Street suite 103 Marlborough, MA 01752 services: medical 7/12/19 Planned Parenthood League of Western MA Center 3550 Main Street suite 201 Springfield, MA 01107 services: medical and surgical Deficiencies were cited.	C 000		
C 030	140.103(C)(1) Licensing Requirements - Prior Approvals (C) Prior Approvals. As a prerequisite for a license, all applicants must obtain and submit the following documents in support of the application for licensure:	C 030		

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MA Division of Health Care Facility Licensure and Certification
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE 09/13/19

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4174	A. BUILDING: _____ B. WING _____	07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	**1055 COMMONWEALTH AVENUE BOSTON, MA 02215**

(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
C 030	Continued From page 1 (1) a copy of the certificate of inspection issues pursuant to M.G.L. c. 111 s. 51 by a building inspector of the Department of Public Safety stating that the clinic and any satellite clinic premises comply with the Department's requirements governing egresses, fire prevention, and fire extinguishing apparatus; This ELEMENT is not met as evidenced by: Based on documentation review and interview, the Clinic failed to obtain current inspections from the Department of Public Safety (DPS). Findings include: During review of documentation, Surveyor #1 noted that the DPS certificate for the parent Clinic expired on 5/6/19, and the DPS certificate for the satellite in Marlborough expired 6/28/19. During an interview on 7/3/19 at 10:50 A.M., the Chief Financial Officer confirmed that both DPS certificates had expired, and said that they were waiting for inspections to be completed for both locations.	C 030		
C 070	140.123 Posting of License and DPS Certificate The current license from the Department, and copies thereof, and the current Department of Public Safety (DPS) certificate, where relevant,	C 070		

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	4174	A. BUILDING: _____ B. WING _____	07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	1055 COMMONWEALTH AVENUE BOSTON, MA 02215

(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
C 070	Continued From page 2 shall be posted in a conspicuous place in the clinic, and in any of its satellite clinics. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to post the Department of Public Safety (DPS) certificate of inspection. Findings include: During the environmental tour of the parent Clinic on 7/3/19 at 10:00 A.M., accompanied by the Health Center Manager, Surveyors #1 and #2 did not observe a posted DPS certificate. The Health Center Manager confirmed that the DPS certificate was not posted.	C 070		
C 130	140.206 Janitor's Closet Each clinic shall provide one or more suitably located janitor's closets equipped with a service sink or floor receptacle with hot and cold water for emptying and cleaning housekeeping equipment. A limited services clinic that is located on the premises of another entity may store supplies in a janitor's closet or other designated space provided by that entity provided that the janitor's closet or other designated space is suitably located. Each janitor's closet must have a door that locks. Each clinic shall label cleaning compounds properly and clearly and store them in a janitor's closet or other locked closet.	C 130		

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	4174	A. BUILDING: _____ B. WING _____	07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	1055 COMMONWEALTH AVENUE BOSTON, MA 02215

(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
C 130	Continued From page 3 This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to ensure that cleaning products were kept in a locked cabinet or closet. Findings include: During the environmental tour of the parent Clinic, accompanied by the Manager, on 7/3/19 at 10:05 A.M., Surveyor #1 and #2 observed cleaning products stored in unlocked cabinets under the sinks (in rooms #1, H and in an unnumbered room across from room #1): Virex Tb 946 ml bottle Alconox powered precision cleaner 4 lbs Accompanied on the tour by the Health Center Manager, she confirmed the chemicals were unlocked and accessible. During the environmental tour of the Worcester location, on 7/3/19 at 11:10 A.M., accompanied by the Manager, Surveyor #4 observed that the janitor's closet contained cleaning products, and the door was not locked. The Manager had the Building Manager lock the door, and said that it would be kept locked.	C 130		
C 250	140.211(D) Maintenance & Sanitation - Steriliz Equip Each clinic shall maintain sterilization equipment adequate to the needs of the clinic, for the purpose of sterilizing equipment and supplies as	C 250		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4174	A. BUILDING: _____ B. WING _____	07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	1055 COMMONWEALTH AVENUE BOSTON, MA 02215

(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
C 250	Continued From page 4 required or shall have an arrangement to obtain such services from a source approved by the Commissioner. A recognized method of checking clinic sterilizer performance shall be in effect. This ELEMENT is not met as evidenced by: Based on documentation review and interview, the Clinic failed to provide staff with the equipment required to perform quality control testing on the autoclave machine (used to sterilize instruments). Findings include: During the environmental tour of the parent Clinic on 7/10/19 at 10:00 A.M., Surveyor #1 reviewed the sterility testing log for the autoclave. The last documented test had been run on 6/4/19. On 6/11/19, a staff member had documented that they ran out of supplies and were unable to run the test. For the week of 6/17/19, a staff member had documented that they ran out of supplies, were unable to run the test, testing supplies were ordered and expected to arrive on 6/19/19. For the week of 6/19/19, a staff member had documented that they ran out of supplies and were unable to run the test. For the week of 6/24/19, a staff member had documented that they ran out of supplies and were unable to run the test. For the week of 7/1/19, a staff member had documented that they ran out of supplies and were unable to run the test.	C 250		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4174	A. BUILDING: _____ B. WING _____	07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	**1055 COMMONWEALTH AVENUE BOSTON, MA 02215**

(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
C 250	Continued From page 5 Surveyor #1's review of the quality control testing directions for the autoclave found that testing was to be conducted on a weekly basis. During an interview on 7/10/19 at 10:27 A.M., the Associate Health Center Manager said that the staff member who performed the quality control testing was no longer employed by the Clinic. She confirmed that the quality control testing had not been performed on a weekly basis. During a follow up discussion by email on 7/10/19 at 12:02 P.M., the Associate Health Center Manager informed Surveyor #1 that she had expedited the order for testing supplies, and was working on getting them that day. During a follow up discussion by email on 7/10/19 at 12:03 P.M., the Associate Health Center Manager informed Surveyor #1 that a staff member had taken over the quality control testing and was monitoring the logs for compliance. During a telephone interview with Surveyor #1, on 7/10/19 at 12:49 P.M., the Director of Quality Assurance said that the Clinic would not use the autoclave until staff had been trained to do so, and that they were getting testing supplies from the Worcester location that day.	C 250		
C 320	140.221 Fire Drills Each separate clinic premises shall conduct a fire drill at least twice a year in each work shift, and such drills shall include the entire staff. Documentation of such drills shall be available to the Commissioner for review.	C 320		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4174	A. BUILDING: _____ B. WING _____	07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	**1055 COMMONWEALTH AVENUE BOSTON, MA 02215**

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C 320	Continued From page 6 This ELEMENT is not met as evidenced by: Based on documentation review and interview, the Clinic failed to conduct 2 fire drills per year at the parent and satellite locations. Findings include: Surveyor #1's review of fire drill documentation provided by the Clinic, found that only 1 fire drill was conducted at each Clinic location per year. During an interview on 7/3/19 at 10:50 A.M., the Chief Financial Officer confirmed with the Maintenance Director by email, that the parent Clinic and satellites only conduct 1 fire drill per year.	C 320		

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MA DPH/Division of Health Care Facility Licensure

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4174	A. BUILDING: _____ B. WING _____	06/28/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	**1055 COMMONWEALTH AVENUE BOSTON, MA 02215**

(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
C 000	INITIAL COMMENTS An onsite licensure renewal survey was conducted for the parent clinic: June 20, 2017 Planned Parenthood 1055 Commonwealth Avenue Boston, MA. Services: Medical, Surgical Onsite Licensure renewal surveys were also conducted for the following satellite clinics: June 21, 2017 Planned Parenthood 91 Main Street Marlborough, MA. Services: Medical, Surgical June 21, 2017 Planned Parenthood 470 Pleasant Street Worcester, MA 01609 Services: Medical, Surgical June 22, 2017 Planned Parenthood 391 Main Street Fitchburg, MA 01420 Services: Medical June 28, 2017 Planned Parenthood 3550 Main Street, Suite 201 Springfield, MA 01107 Services: Medical, Surgical A site survey was not conducted for Planned Parenthood: Milford Health Center 208 Main St, Suite 101, Milford MA due to site closure on December 27, 2016.	C 000		

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MA DPH/Division of Health Care Facility Licensure

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	4174	A. BUILDING: _____ B. WING _____	06/28/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	**1055 COMMONWEALTH AVENUE BOSTON, MA 02215**

(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
C 070	140.123 Posting of License and DPS Certificate The current license from the Department, and copies thereof, and the current Department of Public Safety (DPS) certificate, where relevant, shall be posted in a conspicuous place in the clinic, and in any of its satellite clinics. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to obtain a current inspection from the Department of Public Safety, (DPS). Findings include: The Surveyor observed that the DPS certificate posted at the Fitchburg, Marlborough, and Boston sites expired on 4/24/17. When questioned, the Center Manager said that DPS was scheduled to arrive coincidentally with the survey.	C 070		
C 210	140.211 Maintenance & Sanitation Each clinic shall keep supplies and equipment safe,sanitary and in good working condition as necessary for the services offered by the clinic. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to store supplies (specula), in a safe, sanitary manner. Findings include: During the environmental tour of the Boston site,	C 210		

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	4174	A. BUILDING: _____ B. WING _____	06/28/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	1055 COMMONWEALTH AVENUE BOSTON, MA 02215

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C 210	Continued From page 2 on 6/20/17 at 1:30 P.M., the Surveyor observed that the specula were stored in a treatment cart drawer and were not wrapped or covered. There was no material between the specula and the bottom of the drawers. When interviewed, the Center Manager said that the specula were sterilized and placed into the treatment cart drawers. The Center Manager said that the specula were purchased from Cooper Medical. Surveyor review of the Manufacturer's guidelines for care of these specula indicates that: - Thoroughly dried specula should be stored individually in a moisture-free area in a protective tray with partitions. - Protect with cloth or gauze if stored in drawers. During the environmental tour of the Worcester site, on 6/21/17, between 11:30 A.M., and 12:20 P.M., attended by the Center Manager, the Surveyor observed that: the specula were stored in warming drawers, and were not wrapped or covered. There was no material between the specula and the bottom of the drawers. The interior of the drawers appeared lightly soiled. When asked by the Surveyor, the Center Manager said that the specula were sterilized, brought in to each exam room, unwrapped and placed into the drawers. When asked by the Surveyor about the cleaning of the storage drawers, she said that the drawers were cleaned nightly. The Center Manager said that the specula were	C 210		

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C 210	Continued From page 3 purchased from Cooper Medical. Review of the Manufacturer's guidelines for care of these specula indicates: -Thoroughly dried specula should be stored individually in a moisture-free area in a protective tray with partitions. -Protect with cloth or gauze if stored in drawers. The Surveyor reviewed these guidelines with the Center Manager, who said that the specula storage issue was being reviewed by the Clinic. On 6/22/17, at 1:00 P.M., at the Fitchburg site, the Surveyor observed the specula storage with the Center Manager. In exam room #1, specula were stored in covered plastic bins, which were lined with a disposable under pad. The plastic bins were on top of a heating pad. In exam room #2, specula were stored in a warming drawer, which was lined with a disposable underpad, in the exam table. Specula were not stored individually, as is specified in the Manufacturer's guidelines. On 6/28/17, at 11:30 A.M., at the Springfield site, the surveyors observed the specula storage with the Center Manager. The specula were stored in warming drawers, which were lined with disposable under pads, in the exam tables. They were not stored individually, as is specified in the Manufacturer's guidelines.	C 210		
C 300	140.212(C) Linen & Laundry - Storage The clinic shall store clean linen in a closed closet, cabinet, or cart away from soiled areas.	C 300		

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C 300	Continued From page 4 This ELEMENT is not met as evidenced by: Based on observation and interview, the Fitchburg Clinic failed to store soiled linen separately from clean linen. Findings include: On 6/22/17, during the environmental tour, attended by the Nurse Practitioner, the surveyor observed an open, red cloth bag in a metal stand, in the supply room. The Nurse Practitioner said that dirty linen was stored in the bag. The Surveyor observed that a was a rack on which uniforms were hung, next to the red cloth bag. When questioned by the Surveyor, the Nurse Practitioner said that the hanging uniforms were clean.	C 300		
C 320	140.221 Fire Drills Each separate clinic premises shall conduct a fire drill at least twice a year in each work shift, and such drills shall include the entire staff. Documentation of such drills shall be available to the Commissioner for review. This ELEMENT is not met as evidenced by: Based on document review, and interview, the Fitchburg Clinic failed to perform fire drills twice a year as required. Findings include: Surveyor review of the Clinic's fire drill documentation indicated that a fire drill had been conducted once in 2015, on 10/19/15 and once in	C 320		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PRNTHD/PRETRM HLTH SRV-GT B	**1055 COMMONWEALTH AVENUE BOSTON, MA 02215**

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C 320	Continued From page 5 2016, on 6/14/16. During interview, the Center Manager said that a fire drill is scheduled for 6/28/17. The Center Manager said that the Clinic did not have a policy regarding fire drills.	C 320		

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	220110	A. BUILDING _____ B. WING _____	C 07/12/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

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A 000	INITIAL COMMENTS A CMS authorized Substantial Allegation Survey was conducted (ACTS Reference #: MA00031081) on 7/11/19 & 7/12/19 at: Brigham & Women's Hospital 75 Francis Street Boston, MA 02115 The following Conditions of Participation were reviewed using a sample of ten patients. 42 CFR 482.13: Patient Right's 42 CFR 482.21: Quality Assessment & Performance Improvement Program	A 000		
A 283	QUALITY IMPROVEMENT ACTIVITIES CFR(s): 482.21(b)(2)(ii), (c)(1), (c)(3) (b) Program Data (2) [The hospital must use the data collected to -.....] (ii) Identify opportunities for improvement and changes that will lead to improvement. (c) Program Activities (1) The hospital must set priorities for its performance improvement activities that-- (i) Focus on high-risk, high-volume, or problem-prone areas; (ii) Consider the incidence, prevalence, and severity of problems in those areas; and (iii) Affect health outcomes, patient safety, and quality of care. (3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to	A 283		8/31/19

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 08/16/2019

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 283	Continued From page 1 ensure that improvements are sustained. This STANDARD is not met as evidenced by: Based on records reviewed and interviews the Hospital failed for three (Patients #1, #Patient 6 & Patient #7) patients of ten sampled patients to implement opportunities for improvement regarding patient falls after Patient #1's, Patient #6's and Patient #7's adverse events. The Hospital failed to implement opportunities for improvement regarding: 1.) Physician evaluation documentation after a patient fall, 2.) Clear staff instructions of Hospital expectations regarding Physician (or Licensed Independent Provider) notification to evaluate a patient after a fall and 3.) Coordinated instructions between nursing services and transport services for monitoring patients at risk for falls when the patient is off the patient care unit for testing. Findings included: The document titled, Quality Improvement Plan, dated 2019, indicated the Hospital had a process for improvement. The Quality Improvement Plan indicated the Hospital monitored performance by collecting data that allowed the Hospital to decide on improvements.	A 283		

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A 283	Continued From page 2	A 283		

The document titled, Falls Review Process, undated, indicated that a staff nurse, nurse leader or Department Manager was responsible to complete a review of the event, talking to the patient witnesses or staff members who were in proximity and had knowledge of the event.

The Surveyor interviewed the Quality Director at 1:30 P.M. on 7/11/19. The Quality Director said that the Falls Committee reviewed falls; however, the Falls Committee had not met after 4/2018.

The Hospital policy titled, Fall Risk Assessment, dated 9/28/18, indicated that the Hospital called a Rapid Response (emergency response personnel) when a patient fell and struck the head. The Fall Risk Assessment policy did not indicate clear instructions for when staff were expected to contact a Physician (or Licensed Independent Provider) to evaluate a patient after a fall. The Hospital Fall Risk Assessment policy did not indicate instructions for monitoring patients at risk for falls when off the patient care unit for testing.

The Hospital policy titled, Observer, dated 5/31/18, indicated the Hospital implemented either a constant observer (person) or a visual monitor (device) to monitor patients evaluated to have a high risk for fall. The policy did not indicate instructions for monitoring Patients at risk for falls when off the patient care unit for testing.

The Hospital Policy titled, Central Transport Services Stretcher Procedure, dated 7/16/15, indicated that floor (patient care unit) staff accompanied patients on fall precautions (at risk

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A 283	Continued From page 3 for fall). Regarding Patient #1's fall: The History & Physical, dated 10/11/18, indicated that Patient #1 was admitted from a cardiac clinic for a syncopal (fainting) episode and a history of falls. A Nurse's Note, dated at 10:04 P.M. on 10/11/18, indicated the nurse assessed Patient #1 on admission to the Hospital to be at a high risk of falling. A Nurse's Note, dated at 9:42 P.M. on 10/12/18, indicated Patient #1 fell from a stretcher today at approximately 2:30 P.M. while at cardiology. A.) The Surveyor interviewed the Senior Transport Manager at 11:15 A.M. on 7/11/19. The Senior Transport Manager said the nursing staff on the patient care unit documented the patient's fall risk on a document called a Ticket to Ride (a document of communication between patient care unit nursing staff and transport personal). The Senior Transport Manager said the Transport Staff use the Ticket to Ride for the patients fall status. The Hospital provided no documentation that Patient #1's fall risk was appropriately communicated from the nursing staff to the Transport Staff on a Ticket to Ride. B.) Medical Record review indicated no documentation by a physician that evaluated Patient #1 in cardiology after Patient #1's fall.	A 283		

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A 283	Continued From page 4 Medical Record review indicated a physician note at 11:53 A.M. on 10/13/18 regarding Patient #1's fall. The Surveyor interviewed the Quality Director at 7:30 A.M. on 7/12/19. The Quality Director said a physician did not document an evaluation of Patient #1 after the fall in cardiology in Patient #1's medical record. Regarding Patient #6's fall: A Hospital Report, dated 3/15/18, indicated Patient #6 was found dangling out of bed in between the bed siderails, with the torso (chest) out of the bed and head noted on the floor. The Medical Record indicated no documentation that an Emergency Response Team was notified. The Resident Progress Note, dated at 7:44 P.M. on 3/15/19, approximately 12 hours after the fall, indicated a Computerized Tomography (CT) scan of the head and spine showed no acute findings. Medical Record Review indicated no nursing flow sheet documentation regarding Patient #6's fall. Regarding Patient #7's fall: A Hospital Report, dated 6/22/19, indicated Patient #7 had a fall. A Nurse's Note, dated at 11:25 A.M. on 6/22/19, indicated Patient #7 at 11:19 A.M. had a fall. Medical Record Review indicated no Provider documentation on the day of the fall of an evaluation after Patient #7's fall on 6/22/19.	A 283		

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A 000	INITIAL COMMENTS A CMS authorized Substantial Allegation Survey was conducted (ACTS Reference Number: MA00031021) on 5/2/19 and 5/3/19 at: Brigham and Women's Hospital 75 Francis Street Boston, MA 02115 The following Condition of Participation was reviewed using a sample of ten patients: 42 CFR 482.51: Surgical Services The following Condition of Participation was out of compliance.	A 000		
A 940	42 CFR 482.51: Surgical Services SURGICAL SERVICES CFR(s): 482.51 If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. This CONDITION is not met as evidenced by: The Hospital was out of compliance with the Condition of Surgical Services. Findings included: The Hospital failed to assure that policies regarding surgical counts were effective and	A 940		6/7/19

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A 940	Continued From page 1 ensured all surgical items were accounted for and not retained in patients after surgery.	A 940		
A 951	Refer to TAG: A-0951. OPERATING ROOM POLICIES CFR(s): 482.51(b) Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care. This STANDARD is not met as evidenced by: Based on record review and interview the Hospital failed to ensure that policies regarding surgical counts were effective and that all surgical items were accounted for and not retained in patients after surgery. Findings include: 1. Patient #1 was scheduled to have an open splenectomy on 2/17/19. Patient #1's splenectomy was completed and the surgical counts were performed two times and were reported as correct. After the surgery Patient #1 was transferred to the Post Anesthesia Care Unit (PACU) where he/she became hypotensive (low blood pressure)requiring vasopressors (medications used to treat hypotension). A bedside ultrasound (imaging which uses sound waves to produce pictures of inside the body) was performed showing signs of bleeding. Patient #1 was brought back to the Operating Room (OR) where a retained malleable retractor (from the previous surgery) was discovered	A 951		6/7/19

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A 951	Continued From page 2 inside the patient. 2. Patient #2 underwent a bilateral lung transplant on 3/12/19. From 3/12/19 to 3/21/19, Patient #2 returned to the OR multiple times to have the vacuum dressing (a negative pressure dressing for wounds) changed along with multiple surgical sponges being removed and replaced. Patient #2's Operative Note, dated 3/21/19, indicated that all surgical sponges were removed and the chest was closed. On 3/22/19, Patient #2 received an x-ray revealing a retained surgical sponge. On 3/26/19, Patient #2 returned to the OR for removal of the retained sponge. The Surveyor interviewed the Risk Manager on 5/2/19 at 8:30 A.M. The Risk Manager said that Patient #1's case was reviewed by a multidisciplinary group on 2/18/19. The Risk Manager said that, in Patient #1's case, the Surgical Scrub counted a retractor that was still in use during the surgery and the Circulating Nurse acknowledged the count. The Risk Manager said that, at some point after the count was completed, the retractor was retained in Patient #1's abdomen. The Risk Manager said that the count process was reviewed and it was determined that the Count Policy needed to be changed. The Risk Manager said Patient #2 required multiple wound packing procedures in the OR where multiple sponges were being removed and replaced over several days. The Risk Manager said that, on 3/21/19, the Operative Note indicated that all sponges were removed before the wound was closed. The Risk Manager said that the Count Policy did not address this type of scenario (where a patient received multiple surgical dressing changes) and	A 951		

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BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

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A 951	Continued From page 3 that corrective measures were being reviewed. Review of the document titled "Collaborative Case Review", dated 4/24/19, indicated that the Hospital determined the surgical instrument count policy was ambiguous and the review group discussed recommendations for changing the current policy. The Surveyor interviewed the Nurse Manager of the OR on 5/2/19 at 10:00 A.M. The Nurse Manager said that the Count Policy was vague and was not clear about counting instruments that were in use and could be visualized by staff. The Nurse Manager said that a new policy was developed that corrected this with an added second step/count that would prevent this event from re-occurring. The Nurse Manager said that the new policy was yet to be approved and it needed to be reviewed by two or three more committees. The Nurse manager acknowledged that the Count Policy had not been updated with changes as of 5/2/19. The Nurse Manager said that the Count Policy changes were discussed in the April 2019 staff meeting so that all staff would be aware of the policy change. The Nurse Manager said that staff meetings are available to be reviewed by staff who were unable to attend. The Nurse Manager said there was no process in place to ensure all OR staff were aware of the changes prior to the policy being approved. The Nurse Manager acknowledged that it was possible that some OR staff were unaware of the practice/policy changes. The Hospital provided the Surveyors with an updated draft policy titled "Surgical Counts and Prevention of Retained Surgical Items (RSI)" on	A 951		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	220110	A. BUILDING _____ B. WING _____	C 05/03/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	**75 FRANCIS STREET BOSTON, MA 02115**

(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) COMPLETION DATE
A 951	Continued From page 4 5/9/19. The draft policy addresses a new process for counting instruments including "a count verified upon final closure" and a new process for counting sponges that includes "an X-ray being taken upon permanent closure to assure all packing has been removed". The Risk Manager acknowledged that the draft policy had not yet been approved.	A 951		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	220110	A. BUILDING: _____ B. WING _____	03/06/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	**75 FRANCIS STREET BOSTON, MA 02115**

(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
P 000	INITIAL COMMENTS A State Licensure Survey (ACTS #MA00030775 and ACTS #MA00030883) was conducted on 3/5/19 and 3/6/19 at: Brigham and Women's Hospital 75 Francis Street Boston Ma 02115 Deficiencies related to MA00030883 were cited.	P 000		
P 024	130.200 INCORPORATION OF M'CARE CONDITIONS OF PARTIC Each hospital shall meet all of the requirements of the Medicare Conditions of Participation for Hospitals, 42 C.F.R. 482.11 through 482.62 (hereinafter Conditions of Participation), and as they may be amended from time to time, except the requirement for institutional plan and budget specified in 42 C.F.R. 482.12(d), for utilization review specified in 42 C.F.R. 482.30, the requirement for compliance with the Life Safety Code specified in 42 C.F.R. 482.41(b), and any requirement that conflicts with the supplementary standards in 105 CMR 130.000 Subparts C and D. This REQUIREMENT is not met as evidenced by: A-0450 §482.24(c)(1) - All patient medical record entries must be legible, complete, dated, timed, and	P 024		3/18/19

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	220110	A. BUILDING: _____ B. WING _____	03/06/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

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P 024	Continued From page 1 authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. Based on records reviewed and interview the Hospital failed to adhere to its' policy and procedure for Informed Consent for one of two patients (Patient #1) requiring Informed Consent. The Hospital Policy titled Informed Consent, dated 4/2018, indicated that after the physician has provided the necessary information to the patient and the patient agrees to the procedure, both the patient and the physician must sign, date and time the consent. a.) The Surveyor reviewed Patient #1's Informed Consent for a cardiac catheterization procedure on 3/5/19. The Informed Consent, dated 1/29/19, was left unsigned by the physician. b.) The Surveyor further reviewed Patient #1's Informed Consent for a cardiac catheterization procedure. Under the section titled additional procedures planned or comments there were three hand-written entries that were illegible to the Surveyor. The Risk Manager was asked to review the entries and was only able to determine a few words.	P 024		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	220110	A. BUILDING _____ B. WING _____	C 05/17/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

(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) COMPLETION DATE
A 000	INITIAL COMMENTS A CMS Substantial Allegation Complaint Survey (ACTS Reference # MA00026121) was conducted on 5/8, 5/10, 5/15, 5/17/17 at: Brigham and Women's Hospital 75 Francis Street Boston, MA 02115 The following Conditions of Participation were reviewed using a sample of ten patients: 482.22 Medical Staff 482.23 Nursing Services 482.27 Laboratory Services	A 000		
A 049	MEDICAL STAFF - ACCOUNTABILITY CFR(s): 482.12(a)(5) [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. This STANDARD is not met as evidenced by: Based on documents reviewed and interviews the Medical Staff failed to ensure the quality of care provided to patients for 4 (Patients #2, #3, #4, and #9) of 7 Neonatal Intensive Care Unit (NICU) patients in a total sample of 10 patients who had procedures, diagnostic studies or heart surgery performed at Hospital #2. Findings included: Hospital #1 policy titled, Use of Hospital Blood Products at Hospital B, dated 3/20/17, indicated staff administered blood products issued by Hospital #1 at Hospital #2. The policy indicated that a Blood Transfusion Record was available in	A 049		7/10/17

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 06/30/2017

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

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A 049	Continued From page 1	A 049		

Hospital #2's operating room for documentation. The policy indicated that operating room staff documented other information in Hospital #2's operating room notes. The policy indicated that Hospital #2's operating room Registered Nurses documented blood products issued by the Hospital #1 and administered in Hospital #2's operating room. The policy indicated that Hospital #2 reported to Hospital #1, blood product transfusion reactions of blood issued from Hospital #1 and administered at Hospital #2.

The reference book titled Standards for Blood Banks and Transfusion Services, 30th Edition, dated 4/21/16 page 45 and Standard # 5.29, indicated the patient's medical record included the date and time of transfusion, pre-transfusion and post-transfusion vital signs, the volume of blood transfused, the transfusionist and, if applicable, transfusion-related adverse events.

The Surveyor interviewed NICU Charge Nurse #1, at 9:15 A.M. on 5/8/17. NICU Charge Nurse #1 said that patients (NICU babies) had gastrointestinal procedures, imaging studies, and cardiac surgery for Patent Ductus Arteriosus (PDA, heart defect) conducted at Hospital #2 and the NICU babies returned to Hospital #1 after the procedure, diagnostic study or PDA heart surgery.

NICU Charge Nurse #1 said that Patients #2, #3 and #4 had a jejunostomy feeding tube (tube placed into the infant's intestine) procedure conducted at Hospital #2.

Medical records of Patients #2, #3 and #4 indicated the nurses fed babies by a jejunostomy

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BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

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A 049	Continued From page 2 feeding tube. Medical records of Patients #2, #3 and #4 indicated no documentation by the providers at Hospital #2 of the jejunostomy feeding tube procedure placement or the response of Patients #2, #3 and #4 to the jejunostomy feeding tube placement. The Physician Note, dated 5/28/17 at 10:25 A.M., indicated Patient #9 had heart surgery for a PDA ligation. The medical record did not indicate any documentation regarding the procedure performed by the surgeon, care provided, monitoring and medications administered by the anesthesiologist or operating room staff at Hospital #2, or documentation of blood product administration by staff caring for Patient #9 during surgery performed at Hospital #2.	A 049		
A 582	ADEQUACY OF LABORATORY SERVICES CFR(s): 482.27(a) The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets the requirements of part 493 of this chapter. This STANDARD is not met as evidenced by: Based on interviews and documentation review for one (Patient #9) for a total sample of ten patients, Hospital #1 failed to have in their Transfusion Medicine policies and procedures a procedure to ensure Hospital #2 reported to Hospital #1 a blood transfusion reaction, if one was to occur in Hospital #2. Findings include:	A 582		8/1/17

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A 582	Continued From page 3 The Surveyor interviewed the Neonatal Intensive Care Unit (NICU) Nurse Director on at 9:15 AM on 5/8/17. The NICU Nurse Director said when surgery was indicated for a NICU patient, blood from Hospital #1 would be brought over to Hospital #2 and if needed would be administered by staff at Hospital #2. The Contract between Hospital #1 and Hospital #2, dated March 16, 2016 regarding laboratory medicine, indicated that both Hospital #1 and Hospital #2 will be compliant with regulatory standards. There was not an individual procedure requiring Hospital #2 to report and document a transfusion reaction (if one was to occur) to Hospital #1 so that this information would be available for the care of patients at Hospital #1. A Memo, dated 5/10/17, indicated Hospital #1's NICU patients do at times go to Hospital #2's operating room for certain cardiac procedures and then return immediately to Hospital #1. Hospital #1's NICU patients do travel with a unit of packed red blood cells released from Hospital #1's Blood Bank. If a transfusion reaction was to occur while at Hospital #2, Hospital #2's blood bank would investigate the reaction if one was to occur and then report the information back to Hospital #1.	A 582		

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	220110	A. BUILDING: _____ B. WING _____	08/31/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

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P 000	INITIAL COMMENTS A State licensure complaint investigation was conducted (ACTs Reference Number MA00025402) on 8/31/16 at: Brigham & Women's Hospital 75 Francis Street Boston, MA 02111	P 000		
P 024	130.200 INCORPORATION OF M'CARE CONDITIONS OF PARTIC Each hospital shall meet all of the requirements of the Medicare Conditions of Participation for Hospitals, 42 C.F.R. 482.11 through 482.62 (hereinafter Conditions of Participation), and as they may be amended from time to time, except the requirement for institutional plan and budget specified in 42 C.F.R. 482.12(d), for utilization review specified in 42 C.F.R. 482.30, the requirement for compliance with the Life Safety Code specified in 42 C.F.R. 482.41(b), and any requirement that conflicts with the supplementary standards in 105 CMR 130.000 Subparts C and D. This REQUIREMENT is not met as evidenced by: A-0144 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe	P 024		9/14/16

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P 024	Continued From page 1 setting. This STANDARD is not met as evidenced by: Based on records reviewed and interview the Hospital failed to ensure that Neonatal Intensive Care Unit (NICU) staff checked and documented 4 of 4 Code (Emergency) Carts in 16 of 30 months, consistent with Hospital policy. Findings included: Hospital policy titled Checking Neonatal Emergency Equipment, dated 9/21/15, indicated that the assigned Registered Nurse (RN) would verify that the neonatal code cart was intact at a minimum of every 24 hours. Hospital policy titled Code Cart Control, Inspection and Maintenance, dated 1/2013, indicated the Nursing Services was responsible for checking and documenting the integrity of the code cart lock at a minimum of once a day. Hospital Policy titled Code Cart Exchange, dated 3/2016, indicated the unit staff was responsible for checking and documenting the integrity of the code cart at minimum of once a day. The following 16 of 30 documents titled Neonatal Code Cart Checklist; indicated staff did not check & document the integrity of the Code Carts in the NICU: Dated 3/2016, location not documented, 1 of 31 days; Dated 3/2016, location not documented, 4 of 31 days; Dated 7/2016, location not documented, 1 of 31	P 024		

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P 024	Continued From page 2 days; Dated 4/2016, NICU A, 1 of 30 days; Dated 5/2016, NICU A, 1 of 31 days; Dated 3/2016, NICU B, 10 of 31 days; Dated 3/2016, NICU B, 2 or 31 days; Dated 5/2016, NICU B, 3 of 31 days; Dated 6/2016, NICU B, 1 of 30 days; Dated 4/2016, NICU C, 2 of 30 days; Dated 5/2016, NICU C, 2 of 31 days; Dated 8/2016, Growth & Development Unit (GDU), 1 or 31 days; Dated 8/2016, Neighborhood 2, 1 of 31 days; Dated 4/2016, Adult Code Cart, 3 of 30 days; Dated 6/2016, Adult Code Cart, 1 of 30 days; Dated 8/2016, Adult Code Cart, 1 of 31 days. The Surveyor interviewed the Clinical Nurse Educator at 9:45 A.M. on 8/311/16. The Clinical Nurse Educator said that the NICU had an Adult Code Cart for emergencies of parents and visitors of NICU babies.	P 024		

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	220110	A. BUILDING _____ B. WING _____	C 02/16/2016

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BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

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A 000	INITIAL COMMENTS A substantial allegation survey (ACTS # MA00024737) was conducted on 2/11/16 and 2/16/16 at: Brigham and Women's Hospital 75 Francis Street Boston, MA 02115 The Condition of Participation of Patient Rights (482.13) was reviewed using a sample of 10 patients. A deficiency was cited.	A 000		
A 131	PATIENT RIGHTS: INFORMED CONSENT CFR(s): 482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This STANDARD is not met as evidenced by: Based on record reviewed and interview the Hospital failed to follow the Hospital's internal policy and procedure for activating the Health Care Proxy (HCP) in three of five patients (Patient #1, Patient #5 and Patient #6) who lacked the capacity to make health care decisions. Findings included:	A 131		3/28/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/31/2016

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A 131	Continued From page 1 The Hospital policy titled Health Care Proxies and Living Wills, dated 9/13, indicated the physician was to document in the medical record the determination of the patient's lack of capacity to make health care decisions and indicate the surrogate decision maker (i.e. the Health Care Proxy, Legal Guardian or Next of Kin). Patient #1 was diagnosed with respiratory failure and was treated with sedation and mechanical ventilation. Patient #1 underwent three invasive procedures on 2/7/16; a bronchoscopy (visualization of the lungs), the insertion of a central line (an intravenous line into a major blood vessel) and the insertion of an arterial line (a catheter inserted into an artery). These procedures required informed consent and were signed by Patient #1's family member. The Medical Record lacked the physician's determination of Patient #1's lack of capacity to make health care decisions and the activation of the Health Care Agent was not written until the time of survey at 8:30 A.M. on 2/11/16. Patient #5 was post-operative from an abdominal surgery. Patient #5 was treated with sedation and mechanical ventilation. Patient #5 required multiple procedures requiring informed consent (i.e. surgery, the insertion of a central line, blood transfusion and an invasive heart tracing) that were signed by Patient #5's family member. The Medical Record lacked the physician's determination of Patient #5's lack of capacity to make health care decisions and the activation of the Health Care Agent. The Surveyor interviewed one of Patient #5's	A 131		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A 131	Continued From page 2 physicians at 1:45 P.M. on 2/11/16. The physician said she was not familiar with the process to activate the surrogate decision maker. Patient #6 was diagnosed with altered mental status and respiratory failure and was treated with sedation and mechanical ventilation. The Medical Record lacked the physician's determination of Patient #6's lack of capacity to make health care decisions and the activation of the surrogate decision maker.	A 131		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	220110	A. BUILDING _____ B. WING _____	C 01/20/2015

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A 000	INITIAL COMMENTS A CMS authorized substantial allegation survey was conducted (ACTS Reference Number MA00022806) on 1/8, 1/12, 1/13, 1/14, 1/15 and 1/20/15 at: Brigham and Women's Hospital 75 Francis Street Boston, MA 02115 The following Conditions of Participation were reviewed using a sample of 10 patients. 482.12 Governing Body 482.13 Patient Rights 482.22 Medical Staff 482.23 Nursing Services 482.25 Pharmaceutical Services 482.42 Infection Control	A 000		
A 131	PATIENT RIGHTS: INFORMED CONSENT CFR(s): 482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. This STANDARD is not met as evidenced by: Based on records reviewed, and staff interview, the Hospital failed to ensure an authorized representative, as allowed by State law, signed	A 131		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/10/2015

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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	220110	A. BUILDING _____ B. WING _____	C 01/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	75 FRANCIS STREET BOSTON, MA 02115

(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) COMPLETION DATE
A 131	Continued From page 1 informed consent for invasive procedures in two of two incapacitated patients (Patient #6 and #7) in a total sample of ten patients. The Health Care Proxy was not activated by the attending physician in the medical record as required by Hospsital policies and procedures. Findings include: The Hospital policy titled Health Care Proxies and Living Wills, dated August 2013, indicated the attending physician makes the determination that a patient lacks the capacity to make healthcare decisions. The attending physician must document the determination of incapacity and the surrogate decision maker in the patient's medical record. The medical record for Patient #6 indicated he/she had respiratory failure, was ventilator dependent and sedated. Informed consent forms for Patient #6 indicated the Health Care Proxy signed the informed consents for bronchoscopy (a medical test to view the airways and lungs) and the placement of an arterial line (a thin catheter inserted into an artery.) The medical record did not indicate the Health Care Proxy was activated by the attending physician as required by Hospital policy. The medical record for Patient #7 indicated he/she had dementia. The informed consent form for Patient #7 indicated the Health Care Proxy signed the informed consent for a tracheostomy (a surgical procedure to create an opening through the neck.) Review of Patient #7's informed consent form indicated Patient #7's Health Care Proxy signed the informed consent	A 131		

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A 131	Continued From page 2 for the tracheostomy procedure. The medical record did not indicate the Health Care Proxy was activated by the attending physician as required by Hospital policy. The Surveyor interviewed the Medical Director of the Medical Intensive Care Unit (MICU) at 1:00 P.M. on 1/14/15. The Medical Director of the MICU said that the Attending Physician is required to enter a note into the Progress Notes when a Health Care Proxy is activated.	A 131		
A 347	MEDICAL STAFF ORGANIZATION & ACCOUNTABILITY CFR(s): 482.22(b)(1), (2), (3) The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. (1) The medical staff must be organized in a manner approved by the governing body. (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy. (3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following: (i) An individual doctor of medicine or osteopathy. (ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located. (iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.	A 347		

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A 347	Continued From page 3 This STANDARD is not met as evidenced by: Based on record review and interview, the Hospital failed to ensure that the Medical Staff adhered to the Hospital's Guidelines for the Prevention of Intravascular Catheter Related Infections for one of ten sampled patients (Patient #4). Findings include: 1) The Hospital's Infection Control Policy titled Guidelines for Prevention of Intravascular Catheter Related Infections, approved 10/12/11, indicated that a Peripherally Inserted Central Catheter (a PICC is an intravenous access that can be used for a prolonged period of time) was to be removed if there was clinical evidence of a catheter infection. The Nurses Notes dated, 10/7/14 at 5:00 A.M., indicated Patient #4 experienced rigors (a sudden feeling of cold with shivering) and malaise (a condition of general bodily weakness). The Interdisciplinary Progress Note, dated 10/7/14 and signed by Patient #4's Attending Physician, indicated Patient #4 had an increase in white blood cells (WBC s) from 7000 to 11,000 (normal is 4500 to 10,000; an increase may indicate infection) and reported chills. The Attending Physician Note indicated a concern for PICC line infection and that the PICC line would likely need to come out. The Physician Orders, at 8:15 A.M. on 10/7/14, indicated Vancomycin (an antibiotic) 1000	A 347		

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A 347	Continued From page 4 milligrams (mg) to be administered every twelve hours (no duration indicated in the order) for Patient #4. The medication administration record indicated Vancomycin 1000 mg was administered to Patient #4 beginning at 8:48 A.M. on 10/7/14. The Physician Progress Note, dated 10/8/14 at 3:20 A.M., indicated Patient #4 had a temperature of 100.8 degrees Fahrenheit (normal is 97.8 to 99 Fahrenheit) and had a low blood pressure. The Surveyor interviewed Hospital Physician #1 at 7:20 A.M. on 1/20/15. Hospital Physician #1 said Patient #4's PICC line was not discontinued. Hospital Physician #1 said he believed there was a team discussion about asking for an Infectious Disease consult, but Hospital Physician #1 did not believe this happened. Hospital Physician #1 said it was decided that Patient #4's symptoms of infection were related to the series of injections into his/her knees. Patient #4's medical record entries from 10/7/14 through 10/25/14 did not indicate the knee injections as a possible cause for the symptoms of chills, malaise, fever or increase in WBC count. The Hospital policy Guidelines for Prevention of Intravascular Catheter Related Infections, a patient with a PICC line and clinical signs of infection i.e. rigors, malaise, temperature and elevated WBCs would require careful assessment of the insertion site for erythema (redness), induration (swelling) or purulence (pus). The Guideline also indicated the biopatch and transparent dressing were to be changed	A 347		

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A 347	Continued From page 5 every 7 days or when the dressing became loosened or soiled. The Nurses Notes, dated 10/8/14, indicated Patient #4 was due for a PICC line dressing change. The Nurses Notes indicated, Patient #4 postponed the dressing change and no evidence of an insertion site assessment was present in Patient 4's medical record through 10/25/14. The Physician Orders, dated 10/7/14 at 8:15 A.M., indicated Patient #4's PICC line dressing was to be changed by Registered Nurse #7 and it was " ok to go longer than seven days." This was contradictory to the PICC catheter dressing change policy and accepted standards of care. The Surveyor interviewed Registered Nurse #7 at 3:00 P.M. on 1/14/15. Registered Nurse #7 was named in the Physician Order dated 10/8/14 as the Registered Nurse that Patient #4 would allow to change his/her PICC line dressing. Registered Nurse #7 said Patient #4 was fixated on something happening to the PICC line and would not allow just any Registered Nurse to change the dressing.	A 347		
A 405	ADMINISTRATION OF DRUGS CFR(s): 482.23(c)(1), (c)(1)(i) & (c)(2) (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice. (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners	A 405		

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A 405	Continued From page 6 not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations. (2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures. This STANDARD is not met as evidenced by: Based on record review and staff interview, for one of ten sampled patients (Patient #4), the Hospital failed to ensure that nursing staff documented from 6/6/14 to 12/19/14 that Patient #4's routine daily medications were self-administered and 2) reported to nursing leadership that personal private staff were practicing nursing by accessing a peripherally inserted central catheter (PICC). Findings include: The Hospital's policies and procedures related to Nursing Medication Administration indicated that only a registered nurse, licensed practical nurse or student nurse will administer medications to ensure safe medication administration practices. Hospital policies and procedures related to Patient Self-Administration of Medications indicated that the physician will write an order for a patient to store medication at the bedside and to self-administer the medication. The policy	A 405		

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A 405	Continued From page 7	A 405		

indicated the nurse will assess the patient's ability to self-administer the ordered medications and the nurse will record the medication as self-administered.

The Hospital policy and procedure titled Private Duty Nursing Personnel indicated that private duty personnel may assist in the care of patients and the care is limited to the provisions of activities of daily living and companionship measures.

The Physician Order, dated 6/7/14 at 3:53 P.M., indicated that it was okay for the medications to be administered by Patient #4's personal staff according to their schedule. The Order was contrary to Hospital policy and procedure because private duty nurses may not administer medications to patients. The Physician's Order was transcribed by a hospital registered nurse.

The Physician Order, dated 6/9/14 at 5:37 P.M., indicated that Patient #4 may self-administer routine medications, but all controlled substances must be administered by Hospital nurses.

The Surveyor interviewed Registered Nurse #1 at 9:45 A.M. on 1/13/15. Registered Nurse #1 said 3 of Patient #4's personal staff identified themselves as nurses.

The Surveyor interviewed Registered Nurse #3 at 11:10 A.M. on 1/13/15. Registered Nurse #3 said Patient #4's personal staff identified themselves as nurses. Registered Nurse #3 said that Patient #4's personal staff administered oral, non-controlled medications. Registered Nurse #3 said that Patient #4's personal staff would

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A 405	Continued From page 8	A 405		

then hand her a piece of paper with the date and time Patient #4 took his/her routine daily medications. Registered Nurse #3 said she would then enter the information into Patient #4's electronic medication administration record (eMAR).

The Surveyor interviewed Registered Nurse #4 at 7:45 A.M. on 1/14/15. Registered Nurse #4 said she never witnessed Patient #4 taking his routine medications. Registered Nurse #4 said Patient #4's personal staff provided her with a piece of paper that indicated the date and time Patient #4 took his/her medications. Registered Nurse #4 said she would then enter the administration into Patient #4's eMAR.

The Surveyor interviewed Registered Nurse #5 at 8:00 A.M. on 1/15/15. Registered Nurse #5 said Patient #4's personal staff told her when Patient #4 received routine medications. Registered Nurse #5 said she would then enter the information into Patient #4's eMAR.

The Surveyor interviewed Registered Nurse #6 at 9:00 A.M. on 1/20/15. Registered Nurse #6 said she never saw Patient #4 take his/her routine daily medications. Registered Nurse #6 said Patient #4's personal staff would give Patient #4 his/her routine daily medications. Registered Nurse #6 said Patient #4's personal staff told her when Patient #4 received his/her medications and Registered Nurse #6 would enter the information in the eMAR.

Random review of eMARs, dated 6/6/14 to 12/19/14, indicated Registered Nurse #1, Registered Nurse #3, Registered Nurse #4,

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A 405	Continued From page 9 Registered Nurse #5 and Registered Nurse #6 documented that they administered routine daily medications to Patient #4. The eMARs did not indicate the medications were self-administered by Patient #4 or his/her personal staff. Registered Nurse #1 said Patient #4's personal staff flushed Patient #4's PICC following fentanyl administration by Hospital registered nurses. Registered Nurse #3 said she observed Patient #4's personal staff flushing Patient #4's PICC. Registered Nurse #4 said Patient #4's personal staff flushed Patient #4's PICC. Registered Nurse #4 said she never provided the flush medication to the personal staff because the personal staff had their own supply. The Surveyor interviewed Hospital Physician #1 at 7:30 A.M. on 1/21/15. Physician #1 said he saw Patient #4's personal staff flush Patient #4's PICC. The Surveyor interviewed Nursing Director #1 at 12:50 P.M. on 1/12/15. Nurse Director #1 said she did not think she reported to executive nursing leadership that nursing staff were recording medications administered by Patient #4's personal staff or that Patient #4's private staff were accessing Patient #4's PICC. The Surveyor interviewed Associate Chief Nurse #1 at 10:00 A.M. on 1/13/15. Associate Chief Nurse #1 said Patient #4's visitors, guests and personal staff were not authorized to practice nursing in the Hospital.	A 405		

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A 405	Continued From page 10 The Surveyor interviewed Associate Chief Nurse #2 at 10:30 A.M. on 1/14/15. Associate Chief Nurse #2 said she was not aware the Hospital nursing staff were documenting the administration of Patient #4's routine daily medications based on information provided by Patient #4's personal staff or that Patient #4's personal staff were accessing Patient #4's PICC.	A 405		
A 502	SECURE STORAGE CFR(s): 482.25(b)(2)(i) All drugs and biologicals must be kept in a secure area, and locked when appropriate. This STANDARD is not met as evidenced by: Based on interview and record review, the Hospital failed to ensure that medications for self-administration were kept secure in a patient room, as required by Hospital policies and procedures, for one of ten sampled patients (Patient #4). Findings include: The Hospital's policies and procedures related to Nursing Medication Administration and Patient Self-Administration of Medications indicated the medications ordered for self-administration will be stored in a lockable storage container at the bedside. The Surveyor interviewed Registered Nurse #1 at 9:45 A.M. on 1/13/15. Registered Nurse #1 said Patient #4's routine medications were not kept in a locked place in Patient #4's room. The Surveyor interviewed Registered Nurse #3 at 11:10 A.M. on 1/13/15. Registered Nurse #3 said	A 502		

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A 502	Continued From page 11 Patient #4's routine medications were kept in Patient #4's room and Patient #4 took his/her own medications. Registered Nurse #3 said she had nothing to do with the medications ordered for self-administration. The Surveyor interviewed Registered Nurse #5 at 8:00 A.M. on 1/15/15. Registered Nurse #5 said she did not know where in Patient #4's room his/her routine daily medications were kept. Associate Chief Nurse #1 was interviewed at 12:00 P.M. on 1/14/15. Associate Chief Nurse #1 said the bedside tables on Patient #4's nursing unit, unlike the bedside tables on the other nursing units, did not contain a drawer with a lock to secure medications ordered for self-administration.	A 502		
A 749	INFECTION CONTROL PROGRAM CFR(s): 482.42(a)(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: Based on record review and interview, for 6 of 6 sampled employees (Registered Nurse #3, #4, #7, #8, #9 and Hospital Physician #1) the Hospital failed to ensure that staff consistently adhered to Infection Control practices including Hospital policies for precautions and respiratory protection requirements. Findings include:	A 749		

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A 749	Continued From page 12 1.) The Hospital policy titled Contact Precaution Fact Sheet, dated 8/2013, indicated multi-drug resistant organisms required Contact Precautions. The Hospital policy indicated clean non-sterile isolation gowns must be worn upon entering the room of a patient who is on Contact Precautions. Patient #4's Progress Note, dated 6/10/14, indicated he/she was diagnosed with a multi-drug resistant organism and placed on Contact Precautions. The Surveyor interviewed Nurse Director #1 at 12:50 P.M. on 1/12/15. Nurse Director #1 said the use of precaution gowns by staff was interpreted by Patient #4 as if he/she was dirty. Nurse Director #1 said staff were expected to adhere to the use of personal protective equipment. The Surveyor interviewed Registered Nurse #3 at 11:10 A.M. on 1/13/15. Registered Nurse #3 said she did not wear personal protective equipment when entering Patient #4's room because Patient #4 requested that it not be worn. Registered Nurse #3 said she did not observe other caregivers using personal protective equipment when caring for Patient #4. The Surveyor interviewed Registered Nurse #4 at 7:45 A.M. on 1/14/15. Registered Nurse #4 said Patient #4 was adamant about staff not using isolation gowns. Registered Nurse #4 said she did not wear isolation gowns when caring for Patient #4.	A 749		

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A 749	Continued From page 13 The Surveyor interviewed Registered Nurse #7 at 3:00 P.M. on 1/14/15. Registered Nurse #7 said she often changed Patient #4's Peripherally Inserted Central Catheter (a PICC is an intravenous access that can be used for a prolonged period of time) dressing and was not aware Patient #4 was on Contact Precautions. Registered Nurse #7 said she did not remember any signage indicating precautions and she did not wear an isolation gown when caring for Patient #4. The Surveyor interviewed Physician #1 at 7:20 A.M. on 1/20/15. Physician #1 said he visited Patient #4 five to seven times weekly. Physician #1 said he did not wear an isolation gown because Patient #4 found it offensive. The Surveyor interviewed the Infection Preventionist assigned to monitor Patient #4's unit 1:30 P.M. on 1/14/15. The Infection Preventionist said she had no knowledge of personal protective equipment not being used according to the Hospital policy and staff had not approached her about Patient #4. The Surveyor interviewed Nurse Director #1 at 12:50 P.M. on 1/12/15. The Nurse Director said Patient #4 traveled with a private cook, a personal physician, approximately six (6) attendant staff persons, and a cleaner/helper. The Nurse Director said Patient #4's staff were continuously in attendance of Patient #4's for his/her six (6) month hospitalization. The Nurse Director #1 said Patient #4 referred to his/her personal staff as nurses and the staff would participate in the direct care of Patient #4.	A 749		

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A 749	Continued From page 14 The Surveyor interviewed Registered Nurse #1 at 9:45 A.M. on 1/13/15. Registered Nurse #1 said Patient #4's personal staff would assist with activities of daily living care. The Surveyor interviewed Registered Nurse #3 at 10:35 A.M. on 1/13/15. Registered Nurse #3 said Patient #4's personal staff provided all of Patient #4's care including routine medication administration. The Surveyor interviewed the Infection Prevention Team (Hospital Epidemiologist, Infectious Disease Physician, Infection Preventionists and Occupational Health Director) at 1:30 P.M. on 1/14/15. The Hospital Epidemiologist said the Hospital did not have any policies or procedures in place relating to infection control or immunization that addressed these personal staff. 3.) The Occupational Health Director said the Hospital policy follows the requirements for annual fit testing of Hospital staff who wear an N-95 (a tight-fitting facepiece respirator). The Surveyor interviewed Registered Nurse #8 and #9 at approximately 11:00 A.M. on 1/15/15. Registered Nurses #8 and #9 said they could care for a patient requiring them to use an N-95 respirator. The Surveyor reviewed the health files of Registered Nurse #8 and #9 on 1/20/15. Registered Nurse #8 and #9, who said they would be able to immediately don an N-95 particulate respirator as needed, did not undergo fit testing since 2000 and not annually as	A 749		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	220110	A. BUILDING _____ B. WING _____	C 01/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BRIGHAM AND WOMEN'S HOSPITAL	**75 FRANCIS STREET BOSTON, MA 02115**

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A 749	Continued From page 15 required the Hospital policy.	A 749		

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