EXHIBIT HH

PRINTED: 01/14/2020
FORM APPROVED

MA DPH/Division of Health Care Facility Licensure

RECEIVED
FEB 13 2020
Dept of Public Health
Clinical Laboratory Program

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A304	A. BUILDING: _____ B. WING _____	08/01/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH SERVICES	111 HARVARD STREET BROOKLINE, MA 02446

(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 A State Clinic Licensure Survey was conducted (ACTS Reference #: MA00029096) on 7/31/18 and 8/1/18 at: Women's Health Services 111 Harvard Street Brookline, MA 02446	C 000		
C 071	140.150(B) Influenza Vaccination Each clinic shall ensure that all personnel are vaccinated with seasonal influenza vaccine unless an individual declines vaccination in accordance with 105 CMR 140.150(F). When feasible, and consistent with any guidelines of the Commissioner of Public Health or his/her designee, each clinic shall ensure that all personnel are vaccinated with seasonal influenza vaccine no later than December 15, 2009 and annually thereafter. This REQUIREMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to ensure that all personnel are vaccinated with seasonal influenza vaccine. Findings include: During a review of the binder labeled "Policies and Procedures", the Surveyor did not find evidence of a policy for employee influenza	C 071		

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C 071	Continued From page 1 vaccination. The Surveyor found that 6 of 8 personnel records showed no documentation of employee influenza vaccination status. During an interview on 8/1/18 at 11:36 A.M., the Surveyor asked the Office Manager if there were any additional policies and procedures other than those in the binder. The Office Manager stated that all of the policies and procedures for the Clinic are contained in the binder. The Office Manager and Clinic Nurse Manager were both present, and both acknowledged that the Clinic does not provide influenza vaccinations to its employees. They said that their staff can get them at their other jobs.	C 071		
C 074	140.150(E) Influenza Vaccination - Provide, arrange for Each clinic shall notify all personnel of the influenza vaccination requirements of 105 CMR 140.150 and shall, at no cost to any personnel, provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza, as required pursuant to 105 CMR 140.150(B) and (C), unless an individual declines vaccination in accordance with 105 CMR 140.150(F). This REQUIREMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to provide or arrange for provision of no-cost employee influenza vaccinations for staff having no proof of current immunization or declination. Findings include:	C 074		

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C 074	Continued From page 2 During a review of the binder labeled "Policies and Procedures", the Surveyor did not find evidence of a policy for providing employee influenza vaccinations. The Surveyor found that 6 out of 8 personnel records showed no documentation of employee influenza vaccination status. During an interview on 8/1/18 at 11:36 A.M., the Surveyor asked the Office Manager if there were any additional policies and procedures other than those in the binder. The Office Manager stated that all of the policies and procedures for the Clinic are contained in the binder. The Office Manager and Clinic Nurse Manager were both present and both acknowledged that the Clinic does not provide influenza vaccinations to its employees. They said that their staff can get them at their other jobs.	C 074		
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	C 130		

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C 130	Continued From page 3 closet or other locked closet. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to provide a locked janitor's closet. Findings include: During a tour of the Clinic on 8/1/18 at 9:01 A.M., the Surveyor found the janitor's closet was unlocked with tape over the lock bolt. During an interview on 8/1/18 at 11:36 A. M., the Clinic Nurse Manager acknowledged the lock bolt was covered and and the janitor's closet was unlocked.	C 130		
C 220	140.211(A) Maintenance & Sanitation - Shelf Life The clinic shall discard supplies used for examination and treatment of patients when beyond their shelf life. This ELEMENT is not met as evidenced by: Based on observations and interview, the Clinic failed to remove expired patient care equipment and supplies when the shelf life expired. Findings include: The Surveyors observed at 8:35 A.M. on 7/31/18 one box of sterile injection adaptors located in the basement medication room that expired in April 2017.	C 220		

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C 220	Continued From page 4	C 220		

The Surveyors observed during a tour of the Recovery Room (RR) on 8/1/18 at 8:20 A.M. an endotracheal tube in packaging that was opened, indicating the sterility of the tube was compromised, and the shelf life of the endotracheal tube expired in September 2011.

The Surveyors observed during the tour of the RR two reusable laryngoscopes and blades lying on a table, not covered or packaged to indicate it was designated for emergency equipment. There was no indication that the laryngoscopes and blades received a high-level disinfection ([HLD] kills all microorganisms and high numbers of bacterial spores) and had the potential to touch mucous membranes or skin. The Clinic failed to ensure that they were stored properly to prevent recontamination.

The Surveyors continued observations during the tour of the RR and observed electrodes (used for cardiac monitoring and cardiac defibrillation) which indicated a shelf life that expired in February 2012.

During a tour on 8/1/18 at 8:40 A.M., the Surveyors found 50 additional instances of expired patient supplies throughout the Clinic which included such items as:

- Clean Utility Room: Steri Dot indicators (4) boxes, expired 3/2016
- Dirty Utility Room: sodium chloride (20) 1000 ml containers, expired 3/2015, 3/2016 and 3/2017

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C 220	Continued From page 5 - Supply Closet #1: rubbing alcohol (9) bottles, expired 12/2017 - Supply Closet #2: single element dispersive electrodes (1) box, expired 7/2012 - Crash Cart: Quick Trach (1) expired 10/04, Sheridan Laryngeal mask, expired 3/2015 During an interview on 8/1/18 at 11:36 A.M., the Clinic Nurse Manager confirmed that the expired supplies were present and available for patient use.	C 220		
C 240	140.211(C) Maintenance & Sanitation - Sterilization Each clinic shall sterilize after each use nondisposable equipment and supplies which require sterilization. Single use items shall not be reused. Sterilized materials shall be packaged and labeled in a manner assuring sterility and shall indicate the sterility dates. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to package and label sterilized materials. Findings include: During a tour of the Clean Utility room on 8/1/18 at 8:40 A.M., the Surveyor opened a drawer containing multiple unwrapped surgical instruments together, available for use on patients; they were not packaged, and not labeled to indicate a sterility date. The Surveyor asked Medical Assistant #1 if the instruments	C 240		

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C 240	Continued From page 6 were clean and the Medical Assistant answered that they were clean, and that the instruments should be packaged and labeled with the date they were sterilized.	C 240		
C 310	140.220 Fire Safety Plan Each clinic shall develop and maintain a written plan for dealing with fire. The clinic shall make a copy of the plan available to all staff members. Each fire safety plan shall specify persons to be notified, locations of alarm signals and fire extinguisher, evacuation routes, procedures for evacuating handicapped and nonambulatory patients, and assignments of specific tasks and responsibilities. A copy of the plan shall be posted in a conspicuous area of each separate clinic premises. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to post and distribute a written fire safety plan. Findings include: During a tour of the Clinic on 8/1/18 at 8:34 A.M., the Surveyors observed there was no evacuation or fire safety plans posted throughout the Clinic. During an interview on 8/1/18 at 11:36 A.M., the	C 310		

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C 310	Continued From page 7 Clinic Nurse Manager acknowledged that there were no postings of an evacuation route or fire safety plans available throughout the Clinic. The Clinic Nurse Manager said that the Clinic had not developed any evacuation and fire safety plans.	C 310		
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 interview, the Clinic failed to conduct fire drills at least twice a year. Findings include: During an interview on 8/1/18 at 11:06 A.M., the Surveyors asked to see documentation of the last two fire drills. The Office Manager stated there was no documentation because no fire drills are performed. During an interview on 8/1/18 at 11:36 A.M., the Office Manager confirmed that the Clinic is not performing fire drills. The Office Manager confirmed that fire drills have never been performed at the Clinic and explained that it was because the fire department comes annually to inspect and check the fire alarms.	C 320		
C 370	141.301(B)(4) Administrative Records - Organizational Chart	C 370		

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C 370	Continued From page 8 (B) Adminstrative records shall include: (4) An organizational chart for the entire organization. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to provide an organizational chart for the entire organization. Findings include: Surveyor review of documents failed to find a copy of a current organizational chart for the Clinic. During an interview on 8/1/18 at 12:01 P.M., the Office Manager was unable to provide the Surveyors with an organizational chart that represented the Clinic, when requested.	C 370		
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 establish polices and procedures regarding the preparation and	C 380		

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C 380	Continued From page 9	C 380		

administration of medications in accordance with acceptable standards of practice and state law.

Findings include:

The Clinic's Policy and Procedure Manual, not dated, did not have policies and procedures regarding medication administration. There were no policies and or procedures that included guidance to 1) identify personnel authorized to administer medication, 2) reflected accepted standards of practice such as confirming the "five rights" of medication administration, 3) the compounding of sterile preparations, 4) where, when and how to document in the medical record the administration of medications administered to a patient and 5) the assessment of patients that have received medications.

The Surveyor interviewed the Nurse Manager of the Clinic on 7/31/18. The Nurse Manager said that the Clinic did not have policies and procedures regarding the preparation and administration of medications.

During an interview on 8/1/18 at 8:40 A.M., Medical Assistant #1 told the Surveyor that Medical Assistants draw up Lidocaine into syringes for the Physician to administer. A review of employee records found no indication that they were trained to prepare and appropriately label medication in a syringe.

During an interview on 8/1/18 at 8:24 A.M., the Nurse Anesthetist (CRNA) said that syringes are prefilled a day ahead of time. The CRNA stated that the bag of prefilled syringes had been on the shelf for approximately one week. The CRNA added that many different staff members draw up

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C 380	Continued From page 10 medications, but do not necessarily date them	C 380		
C 400	140.301(B)(5)(b) Administrative Records - Empl Health Policies At a minimum the policies shall address: (b) Employee health policies that assure employees are free of communicable disease. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a policy that addresses employee health to assure employees are free of communicable disease. Findings include: Record review of the binder labeled "Policies and Procedures" did not contain a policy to ensure that employees are free of communicable diseases. Surveyor review of 8 records indicated that the Clinic failed to develop a consistent system to monitor employees' health. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had not developed policies or procedures regarding employee health monitoring.	C 400		
C 420	140.301(B)(5)(d) Administrative Policies - Emerg Care/Equip At a minimum the policies shall address: (d) The provision of emergency care and the retention of emergency equipment appropriate to	C 420		

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C 420	Continued From page 11 the clinic's patient population. This ELEMENT is not met as evidenced by: Based on record review, observation and interview, the Clinic failed to maintain a written policy that addresses emergency care and retention of emergency equipment. Findings include: Surveyor record review of the binder labeled "Policies and Procedures" found that it did not contain a policy on emergency care and retention of emergency equipment. During a tour of the Clinic, expired emergency equipment was observed in the Crash Cart as follows: -(2) Adult Plus Electrode Pads, expired 2/2012 -(1) DP Electrode Pads, expired 12/2014 -(1) Phillips Peel and Stick Pads, expired 1/2009 -(1) Quick Trach, expired 10/2004 -(2) Easy Cap Co2 Detector, expired 3/2014 -(1) ET Tube, expired 9/2011 -(2) LMA Unique Size 4, expired 1/2006 -(1) Aircare ET Tube, expired 4/2018 -(1) Aircare ET Tube, expired 7/2018 -(1) Sheridan Laryngeal Mask, expired 3/2015 -(1) Introducer, expired 9/2012 During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no protocols regarding emergency care, nor retention of emergency equipment applicable to	C 420		

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C 420	Continued From page 12 their patients.	C 420		
C 440	140.310(B)(5)(f) Administrative Policies - Off-Hour Coverage At a minimum the policies shall address: (f) A policy for off-hour coverage posted conspicuously in the clinic and any of its satellite clinics. The policy must ensure compliance with 105 CMR 140.315(B). This ELEMENT is not met as evidenced by: Based on record review, observation and interview, the Clinic failed to maintain a policy to address off-hour coverage. Findings include: Record review of binder labeled "Policies and Procedures" did not contain a policy for off-hours coverage. The Surveyors observed that there was no posting available, visible to patients. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no written policy regarding off-hours coverage.	C 440		
C 450	140.301(B)(5)(g) Administrative Policies - Hazardous Waste At a minimum the policies shall address: (g) The disposal of hazardous and infectious waste.	C 450		

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C 450	Continued From page 13	C 450		

This ELEMENT is not met as evidenced by:
Based on record review, interview and observation, the Clinic failed to develop policies and procedures to address the appropriate disposal of hazardous and infectious waste.

Findings include:

1. Record review of binder labeled "Policies and Procedures" did not contain policies or procedures related to the disposal of hazardous and infectious waste.

During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no written policy regarding the disposal of hazardous and infectious waste.

During a tour of the Clinic on 8/1/18 at 9:36 A.M., the Surveyors observed the contents of an unlocked refrigerator in the Recovery Room (Refrigerator #2). The refrigerator was on the floor, under a table that had a microwave on it.

The Surveyor asked what was in the refrigerator and the Clinic Nurse Manager stated that she thought it was the "Research Fridge." In the refrigerator were unlabeled specimen cups filled with a red liquid. The Clinic Nurse Manager stated that she did not know what was in the specimen cups and believed that the research was something to do with tissue. The Clinic Nurse Manager was unable to provide information about what research is being performed, who is performing the research, or whether there was a written contract or

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C 450	Continued From page 14 agreement regarding the research being performed. Stored in Refrigerator #2 was also one box of injectable medication. 2. During tour on 8/1/18, it was identified that Biohazardous waste was also stored in a freezer in the Clinic. Inside the freezer the surveyors observed eight large plastic containers, which were not labeled. Although the Clinic Nurse Manager confirmed the freezer contained biohazardous waste materials, she was unable to provide any information regarding the Clinic's process for disposing of biohazardous waste. 3. In a closet where biohazard waste was being stored there was a detectable foul odor noted by the Surveyors. A Medical Assistant who accompanied the Surveyors said she did not know what accounted for the foul odor.	C 450		
C 470	140.301(B)(5)(i) Administrative Policies - Clinic Services At a minimum the policies shall address: (i) Services which the clinic provides. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a policy that addresses the services which the clinic provides. Findings include:	C 470		

EXHIBIT HH

PRINTED: 01/14/2020
FORM APPROVED

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
	A304	A. BUILDING _____ B. WING _____	08/01/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH SERVICES	111 HARVARD STREET BROOKLINE, MA 02446

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C 470	Continued From page 15 Record review of binder labeled "Policies and Procedures" did not contain a written procedure or policy detailing the services provided by the Clinic. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no written policies or procedures regarding the services that the Clinic provides.	C 470		
C 480	140.301(B)(5)(j) Administrative Policies - Smoking At a minimum the policies shall address: (j) Smoking on the premises. Such policies shall assure the comfort of all patients including patients in waiting areas. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a policy that addresses smoking on the premises. Findings include: Surveyor review of the binder labeled "Policies and Procedures" did not find any policies regarding smoking at the Clinic. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic has no written policy regarding smoking on the premises.	C 480		
C 490	140.301(B)(5)(k) Administrative Policies - Reportable Dis/Cond	C 490		

EXHIBIT HH

PRINTED: 01/14/2020
FORM APPROVED

MA DPH/Division of Health Care Facility Licensure

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	A304	A. BUILDING: _____ B. WING _____	08/01/2018

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C 490	Continued From page 16 At a minimum the policies shall address: (k) Procedures for complying with laws and regulations relating to reportable diseases and conditions. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a policy that addresses complying with laws and regulations relating to reportable diseases and conditions. Findings include: Record review of binder labeled "Policies and Procedures" did not contain a policies or procedures on complying with laws and regulations relating to reportable diseases and conditions. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no written policy regarding reportable diseases and conditions.	C 490		
C 510	140.301(B)(6) Administrative Policies - Personnel Records (B) Administrative records shall include: (6) Personnel records for each employee, including evidence of any required license or registration number; documentation of any specialty certification, education and job	C 510		

EXHIBIT HH

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FORM APPROVED

MA DPH/Division of Health Care Facility Licensure

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	A304	A. BUILDING: _____ B. WING _____	08/01/2018

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C 510	Continued From page 17 experience. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a policy that addresses the required contents for personnel records. Findings include: Surveyor review of the binder labeled "Policies and Procedures" did not find any policies or procedures to specify what content information was required for personnel records. Each of the 8 employee files reviewed were consistently missing evidence of one or more of the required elements. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no written policy regarding the contents of personnel records.	C 510		
C 580	140.302(B)(5) Patient Records - Orders The record with respect to each patient shall include the following: (5) Orders for any medication, test, or treatment. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to provide written orders for medications and treatments.	C 580		

EXHIBIT HH

PRINTED: 01/14/2020
FORM APPROVED

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
	A304	A. BUILDING: _____ B. WING _____	08/01/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S HEALTH SERVICES	111 HARVARD STREET BROOKLINE, MA 02446

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C 580	Continued From page 18 Findings include: Surveyor review of medical records on 8/1/18 at 1:11 P.M., found that they contained no written orders for medications, treatments, tests. The signature of the Nurse Anesthetist (CRNA) was the only signature documented on medication notes or procedure notes. During an interview on 8/1/18 at 1:11 P.M., the Clinic Nurse Manager confirmed that no written orders are given and that the CRNA knows what dose of each medication needs to be given because they have a special sheet of paper that outlines the dose required for most patients.	C 580		
C 750	140.305(A) Emergency Transfer - Written Agreements Each clinic shall have a written agreement with a nearby hospital providing emergency services for the transfer there of patients for emergency treatment beyond that provided by the clinic. This ELEMENT is not met as evidenced by: Based on interview, the Clinic failed to provide a written agreement with a nearby hospital for transfer of patients requiring emergency services beyond those provided by the Clinic. Findings include: During an interview on 8/1/18 at 11:06 A.M., the Surveyor asked the Office Manager for a copy of a written agreement with a nearby hospital for provision of emergency services. The Office Manager could not provide a written agreement.	C 750		

EXHIBIT HH

PRINTED: 01/14/2020
FORM APPROVED

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
	A304	A. BUILDING: _____ B. WING _____	08/01/2018

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C 750	Continued From page 19 The Clinic Nurse Manager stated that the Clinic has a verbal agreement with a local hospital for the transfer of patients.	C 750		
C 780	140.305(D) Emergency Transfer - Plan and Procedures Each clinic shall have a written plan and procedures for the emergency transfer including the transport of clinic patients. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a written plan that addresses emergency transfer and transports. Findings include: Surveyor review of the binder labeled "Policies and Procedures" did not find a policy or procedure on the emergency transfer of patients. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that all policies are located in the "Policies and Procedures" binder, and if the policy was not in the binder, then the Clinic could not provide one.	C 780		
C 790	140.306 Serious Complaint Procedure Each clinic shall develop a written procedure that assures prompt and complete investigations of all serious complaints that are filed against employees of the clinic or members of its professional staff.	C 790		

EXHIBIT HH

PRINTED: 01/14/2020
FORM APPROVED

MA DPH/Division of Health Care Facility Licensure

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C 790	Continued From page 20 This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a written policy that addresses investigation of serious complaints. Findings include: Surveyor review of the binder labeled "Policies and Procedures" found that it did not contain a policy related to investigations of serious complaints. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no written policy regarding serious complaints. During an interview on 8/1/18 at 1:56 P.M. the Clinic Nurse Manager stated that there were no serious complaint records for the Surveyors to review. Surveyor observation of written staff meeting minutes indicated that there may have been incidents that could qualify as serious complaints requiring investigation.	C 790		
C 860	140.307(A)(1)-(8) Serious Incident Reports A clinic shall immediately report to the Department any of the following which occurs on premises covered by its license: (1) death that is unanticipated, not related to the natural course of the patient ' s illness or	C 860		

EXHIBIT HH

MA DPH/Division of Health Care Facility Licensure

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C 860	Continued From page 21 underlying condition, or that is the result of an error or other incident as specified in guidelines of the Department; (2) full or partial evacuation of the facility for any reason; (3) fire; (4) suicide; (5) serious criminal acts; (6) pending or actual strike action by its employees, and contingency plans for operation of the clinic; (7) reports on surgery and anesthesia-related complications as required by 105 CMR 140.611; or (8) any other serious incident or accident as specified in guidelines of the Department. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a policy that addresses the reporting of serious incidents to the Department. Findings include: Record review of binder labeled "Policies and Procedures" did not contain policies to address serious incidents.	C 860		

EXHIBIT HH

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MA DPH/Division of Health Care Facility Licensure

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C 860	Continued From page 22 During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that the Clinic had no written policy regarding the reporting of serious incidents. During an interview on 8/1/18 at 1:56 P.M., the Clinic Nurse Manager stated that there were no serious incident records for the Surveyors to review. Surveyor review of staff meeting minutes indicated that there may have been instances that qualify as reportable events.	C 860		
C 930	140.314 Nursing Staff Each clinic shall retain a sufficient number of nurses qualified to provide the nursing services necessary to the type of care the clinic provides. These services shall be under the direction of a registered nurse. This ELEMENT is not met as evidenced by: Based observation, record review, and interview, the Clinic's nursing services failed to have the Clinic's Nursing Service under the direction of a registered nurse. Findings include: The Surveyor observed and interviewed an employee who identified herself as the Nurse Manager at 8:00 A.M. on 7/31/18. The Personnel File of the Nurse Manager was reviewed on 7/31/18. The Nurse Manager's file indicated she held a practical nurse license from	C 930		

EXHIBIT HH

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C 930	Continued From page 23 the Commonwealth of Massachusetts and was not a registered nurse.	C 930		
C 980	140.318 In-Service Training for Health Care Staff There shall be a program of on-going in-service training to all staff providing health care services. Such training may include case studies and staff presentations provided within the facility or may be obtained through participation in continuing education courses offered outside the clinic. This ELEMENT is not met as evidenced by: Based on documentation review and interview, the Clinic failed to provide documentation of on-going in-service training for all healthcare staff. Findings include: Employee Records for 4 of 4 selected employees were reviewed and showed no evidence of ongoing inservice training. There was no evidence of a facility orientation, performance evaluations, nor evidence of competencies for nursing care and responsibilities, such as administration of medications to patients in the employee records. During an interview on 8/1/18 at 11:00 A.M., the Nurse Manager said there was no documentation of Orientation to the Clinic, no performance appraisals and no training or competencies in any of the Clinic employee personnel records.	C 980		

EXHIBIT HH

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FORM APPROVED

MA DPH/Division of Health Care Facility Licensure

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C1190	Continued From page 24	C1190		
C1190	140.345(B) Drug Handling & Admin - Emergency Drug Access The clinic shall maintain an emergency medication kit. The emergency medication kit shall be kept in a separate sealed container when not in use. Drugs requiring refrigeration shall be kept in a separate sealed container under proper refrigeration when not in use. Each emergency medication kit shall be prepared, packaged and sealed by a registered pharmacist or pharmacy intern under the direct supervision of a registered pharmacist, and shall contain a list of contents on the outside cover and within the box. After an emergency medication kit has been opened, it shall be inspected, restocked and resealed by a registered pharmacist or a pharmacy intern under the direct supervision of a registered pharmacist the next day the clinic pharmacy is open. This ELEMENT is not met as evidenced by: Based on observation and interview, the Clinic failed to properly maintain an emergency medication kit. Findings include: During inspection of the crash cart, the Surveyor found the cart to be unlocked/unsealed. Within the crash cart was a medication box that was also unlocked and unsealed.	C1190		

EXHIBIT HH

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FORM APPROVED

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
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C1190	Continued From page 25 During interview on 8/1/18 at 8:40 A.M., the Nurse Anesthetist (CRNA) confirmed that the emergency medication kit was unlocked.	C1190		
C1240	140.346(B) Facilities & Equipment - Storage of Drugs Drugs shall be stored under proper conditions to ensure product stability and security. Drug storage facilities shall be locked. Schedule II drugs shall be kept double locked. This ELEMENT is not met as evidenced by: Based on observations the Clinic failed to appropriately store medications in a refrigerator designated for medication storage only and failed to ensure medication security. Findings include: During a tour of the Recovery Room on 8/1/18 at 8:30 A.M., Surveyors observed a box of Nuva Rings (a flexible vaginal ring used to prevent pregnancy) in a refrigerator with perishable food items. Based on observation, the Clinic failed to ensure drug security. During tour of the Clinic on 8/1/18 at 8:30 A.M., the Director of Counseling showed the Surveyors where the medications are stored and stated that it is also the employee break area. During tour of the Clinic on 8/1/18 at 8:40 A.M.,	C1240		

EXHIBIT HH

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FORM APPROVED

MA DPH/Division of Health Care Facility Licensure

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C1240	Continued From page 26 the following medications were found unlocked: Procedure Room #1 -Lidocaine HCl 1% (20 vials) -Lidocaine 300 mg/30 ml HCl injection (7 vials) -Lactated Ringers (10 bags) Procedure Room #2 -Lidocaine 300 mg/30 ml (11 boxes) - (1) Syringe with clear liquid, 20 ml, but labeled to indicate it contained "25 mls Lidocaine 7/31/18" Recovery Room - Atropine 8 mg/ 20 ml (1 vial) - Ondansetron 40 mg/20 ml (1 vial) - Ketorolac Tromethamine 60mg/ 2 ml (5 vials) - Lactated Ringers 500 ml (6 bags) Recovery Room Refrigerator #1 - Nuva Rings (2 boxes) found with a container of hummus, a bag of carrots and an iced coffee Recovery Room Refrigerator #2 - Gardasil (1 box) found with specimen containers of unknown, unlabeled red liquid	C1240		
C1280	140.347(A) Clinics Without Pharmacies - Compliance The clinic must register annually under the Controlled Substances Act with the Department pursuant to M.G.L. c. 94C, § 7 and shall comply	C1280		

EXHIBIT HH

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FORM APPROVED

MA DPH/Division of Health Care Facility Licensure

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C1280	Continued From page 27 with all applicable federal, state, and local drug laws and regulations. This ELEMENT is not met as evidenced by: Based on observations, record review and interviews, the Clinic failed to comply with all federal, state and local drug laws and regulations. See C-1290 and C-1320	C1280		
C1290	140.347(B) Clinics Without Pharmacies - Record System The clinic professional services director or his or her designee shall be responsible for ensuring that a record system is kept that is sufficient to maintain control over the requisitioning and administration of controlled substances. The record keeping system shall comply with all federal and state laws and regulations. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to maintain a record system for maintaining control over requisitioning and administration of controlled substances. Findings include: The Drug Enforcement Administration (DEA) 1304.11(c) Biennial inventory date states: After the initial inventory is taken, the registrant shall take a new inventory of all stocks of	C1290		

EXHIBIT HH

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MA DPH/Division of Health Care Facility Licensure

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C1290	Continued From page 28	C1290		

controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

During record review, the document titled Main Narcotic Log, dated 07/31/2018, did not indicate that the Clinic had ever conducted a biennial inventory.

The Surveyor interviewed the Clinical Nurse Manager on 07/31/18. The Clinical Nurse Manager stated that the Clinic has never conducted a biennial inventory.

The DEA 1304.11 (e)(iii) states: For each controlled substance in finished form the inventory shall include:
(A) The name of the substance;
(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

During record review, the document titled Main Narcotic Log, dated 07/31/2018 did not indicate drug strength for Fentanyl (a Schedule II controlled substance) 10 cc (cubic centimeter or equivalent unit is milliliter or mL) vials. In addition, the dosage unit (tablet, capsule etc.) was not indicated for Midazolam (a Schedule IV controlled substance) 1 mg and Midazolam 5 mg.

EXHIBIT HH

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MA DPH/Division of Health Care Facility Licensure

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C1290	Continued From page 29 The DEA 1304.04 (g) states: Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section. (1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. During record review, the document titled Main Narcotic Log, dated 07/31/2018, indicated that both Fentanyl (Schedule II controlled substance) and Midazolam (Schedule IV controlled substance) were being logged on the same sheet and maintained together, not separately.	C1290		
C1320	140.347(E) Clinics Without Pharmacies - Outdated Drugs 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 observations and interview, the Clinic failed to ensure outdated drugs with the potential	C1320		

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C1320	Continued From page 30	C1320		

for deterioration and microbial growth were stored appropriately so as to maintain their safety and effectiveness and were not available for patient use.

At 8:20 A.M. on 7/31/18, the Surveyor observed in the staff room a cabinet that was doubled locked and made the following observations of medications:

- (3) vials of 20 milliliters (ml) normal saline, expired 1/2018 and 2/2018

- (1) 20 ml vial of Labetalol (medication used to treat high blood pressure), expired 2/2018.

- (2) opened vials of 10 ml Oxytocin (hormone), expired 6/2018. The vial was not labeled to indicate time or date as to when the vials were opened/accessed.

- (1) opened 20 ml vial of Atropine (involuntary nervous system blocker) not labeled with the time or date as to when the medication was opened/accessed

- (5) syringes in a plastic bag that were labeled Brevital (anesthetic). The syringes were not labeled to indicate when they were compounded and failed to indicate a beyond use date.

- (1) opened 50 ml vial of Benadryl (antihistamine), expired 6/2016. The vial was not labeled to indicate time or date as to when the medication was opened/ accessed.

- (1) opened 20 ml vial of Zofran (antiemetic; treatment for nausea and vomiting). The vial was

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MA DPH/Division of Health Care Facility Licensure

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C1320	Continued From page 31	C1320		

not labeled to indicate indicate time or date as to when the medication was opened/ accessed.

- (8) 500 milligrams (mg) vials of Levofloxacin (antibiotic) for intravenous (IV) use, expired 3/2018

- (1) 2 ml vial of Gentamycin (antibiotic), expired 1/2013

- (2) 2 ml vials of Lasix (diuretic), expired 12/2017

- (5) packages Nitroglycerine ointment (dilates blood vessels used to treat and prevent chest pain and used also to treat anal fissure pain), expired 2/2018

- (2) 5 ml syringes of 100 mg of Succinylcholine (paralytic), one syringe expired 2/2018, and the other expired 6/2018

-(1) 10 ml vial of Phenylephrine (decongestant), expired 6/2018

- (1) 1000 ml IV fluid bag of Dextrose (sugar), expired 11/2017

A plastic bag labeled Versed (sedative used for procedural sedation and anesthesia), which contained 15 syringes with attached needles. There was no documentation to indicate the amount of Versed in the syringe, or the time or date as to when the medication was compounded.

A plastic bag labeled Ketamine (anesthetic used for starting and maintaining anesthesia), which contained four syringes with attached needles.

EXHIBIT HH

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MA DPH/Division of Health Care Facility Licensure

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C1320	Continued From page 32 There was no documentation to indicate the amount of Ketamine in the syringe, or the time or date as to when the medication was compounded. A plastic bag labeled Fentanyl (narcotic) which contained (6) 3 ml syringes with attached needles. Each of the (6) syringes were labeled 50 micrograms (mcg) of Fentanyl; however, no date or time when the medication was compounded. The Surveyor interviewed the Nurse Manager during the tour of the Staff Room, where medications were stored and prepared on 7/31/18. The Nurse Manager said the medications in the syringes are prepared as needed and are ready for patient use for the next day. The Surveyors observed at 8:30 A.M. on 8/1/18 (3) Lo Loestrin Fe (birth control) packages with an expiration date of 1/2018. During an interview on 8/1/18 at 8:24 A.M., the Nurse Anesthetist (CRNA) stated that syringes are prefilled a day ahead of time. The CRNA stated that the bag of prefilled syringes had been on the shelf for approximately one week. The CNRA added that many different staff members draw up meds but do not necessarily date them.	C1320		
C1340	140.347(G) Clinics Without Pharmacies - Labling All drugs shall be adequately and distinctly labeled.	C1340		

EXHIBIT HH

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C1340	Continued From page 33 This ELEMENT is not met as evidenced by: Based on observation, record review and interview, the Clinic failed to ensure that all medications were adequately and distinctly labeled. See C-1320	C1340		
C1380	140.351(B) Contracting for Outside Clinical Lab Svcs The clinic must have detailed written statements of policy on procedures for the collection, transport, and handling of specimens referred to such an outside laboratory. These written statements shall be available for review by the Commissioner. This ELEMENT is not met as evidenced by: Based on record review and interview, the Clinic failed to provide a written policy on the collection, transport and handling of specimens referred to an outside laboratory. Findings include: Surveyor review of the binder labeled "Policies and Procedures" did not contain a written policy or procedure or contract regarding specimens referred to outside laboratories. The only outside laboratory records found were receipts of laboratory pickups. During an interview on 8/1/18 at 12:01 P.M., the Office Manager confirmed that all policies were located in the "Policies and Procedures" binder, and if the policy was not in the binder, then the	C1380		

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C1380	Continued From page 34 Clinic could not provide one.	C1380		
C1480	140.370(A) Evaluation of Quality - Program Each clinic shall establish an organized, comprehensive program that is adequate to regularly review and evaluate the quality of care provided. This ELEMENT is not met as evidenced by: The Clinic failed to ensure that they maintained a comprehensive quality assurance program that identified opportunities for improvement within the clinic. It was determined the Clinic failed to develop policies and procedures related to medications, biohazard waste, expired equipment, employee health. The findings include: The Quality Assurance program failed identify significant opportunities for improvement related to the following: 1. Adhering to current standards of practice related to the dispensing, storage, compounding, and labeling of medications. Ensuring that medications were not stored with food items. 2. Ensuring accurate maintenance of records related to controlled substances used in the Clinic. 3. Ensuring policies and procedures were developed and followed related to employee health and training and orientation of Clinic employees.	C1480		

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C1480	Continued From page 35 4. Ensuring clear polices, procedures, and practices related to storage and disposal of biohazardous waste. 5. Ensuring that equipment for use for patients was packaged and labeled to ensure sterility. 6. Ensuring that expired patient equipment and supplies were not available for use at the clinic.	C1480		
C2440	140.601 Medicare COPs for ASCs A clinic licensed to perform surgery must comply with the standards of the Medicare Conditions of Participation for Ambulatory Surgical Services that are set forth in 42 CFR 416.42(a)(l) relating to anesthesia risk and evaluation; 416.44(a)(1) and (2) relating to physical environment; 416.44(c) relating to emergency equipment; and 416.44(d) relating to emergency personnel. Clinics administering general anesthesia shall also comply with 42 CFR 416.44(b) of the Medicare Conditions of Participation relating to safety from fire. This ELEMENT is not met as evidenced by: Based on observations, record review and interview, for 2 (Patient #2 and #3) of 3 patient records sampled and because the Clinic held a license to perform surgery, the Clinic failed to comply with the Medicare Conditions of Coverage for Ambulatory Surgical Services. See C-2450	C2440		

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C2450	Continued From page 36	C2450		
C2450	140.601 (416.42a) Medicare COPs for ASCs - Anesthesia Risk A clinic licensed to perform surgery must comply with the standards of the Medicare Conditions of Participation for Ambulatory Surgical Services that are set forth in 42 CFR 416.42(a)(1) relating to anesthesia risk and evaluation: 416.42(a) Anesthetic Risk and Evaluation A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery. This ELEMENT is not met as evidenced by: Based on record review and interview, for 2 (Patient #2 and #3) of 3 patient records sampled, the Clinic failed to comply with the Medicare Conditions of Coverage for Ambulatory Surgical Services relating to anesthesia risk and evaluation required for clinics holding a license to perform surgery. Findings include: A Medical Note, dated 7/28/18, in Patient #2's medical record indicated that a physician did not examine Patient #2 to identify and evaluate the	C2450		

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C2450	Continued From page 37 risk of anesthesia. A Medical Note, dated 7/28/18, in Patient #3's medical record indicated that a physician did not examine Patient #3 to identify and evaluate the risk of anesthesia. The Surveyor interviewed the Nurse Manager on 8/1/18 at 11:00 A.M. The Nurse Manager said that a physician would listen to a patient's heart and lung sounds only if it was warranted.	C2450		
C2520	140.602(B) Surgical & Anesthesia Privileges - Privileges Anesthesia staff shall be granted privileges to administer anesthesia, including conscious intravenous sedation, only in accordance with their legal and professional qualifications. This ELEMENT is not met as evidenced by: Based on record review and interview the Clinic failed to grant privileges to 4 of 4 providers of anesthesia and surgical care to patients. Findings include: Surveyor reviewed 2 of 2 anesthetists and 2 of 2 attending physician credential files. The credential files of the Clinic failed to include the privileges granted to each of the 2 anesthetists that provide anesthesia care to patients and the 2 physicians who provide surgical care to patients.	C2520		