Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	008444	A. BUILDING: _____ B. WING _____	10/06/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SUBURBAN WOMENS MEDICAL CENTER	17070 RED OAK DRIVE SUITE 505 HOUSTON, TX 77090

(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
A 000	TAC 139 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An unannounced visit was made to the above named facility on 10/06/2015 to conduct a Re-Licensure Survey , to determine compliance with 25 TAC (Texas Administrative Code) Chapter 139 State Licensing Rules for Abortion Facility. An entrance conference was conducted with the Facility's Licensed Vocational Nurse. The purpose of the visit and procedure for the inspection was discussed. The Facility's Licensed Vocational Nurse was provided information/ instruction on completing an acceptable plan of correction. Opportunities were provided for questions and answers about the survey process. An exit conference was conducted on the afternoon of 10/06/2015 with the Facility's Medical Director/ owner. Findings and determination of the inspection was discussed. Deficiencies were cited based on the visit. Information to complete and submit an acceptable plan of correction was given verbally and in writing. Glossary: Ampicillin: is a penicillin antibiotic that fights	A 000	REVIEW POC'S REVIEWED 11/09/2015 CJ Recv'd NOV 03 2015 HFC - Houston	

SOD - [redacted]
LABOR

TITLE: MEDICAL DIRECTOR (X6) DATE: 10/30/15

STATE [redacted] 6H8O11

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A 000	Continued From page 1	A 000		

bacteria. Ampicillin is used to treat or prevent many different types of infections

Autoclave : An autoclave is a pressure chamber used to sterilize equipment and supplies by subjecting them to high pressure saturated steam at 121 °C (249°F) for around 15-20 minutes depending on the size of the load and the contents.

Biological indicator : A biological indicator is a device to monitor the sterilization process that consists of a standardized population bacterial spores known to be resistant to the mode of sterilization being monitored. Biological indicators indicate that all the parameters necessary for sterilization were present.

Ciprofloxin 500 mg: Cipro is fluoroquinolone antibiotic used to treat bacterial infections

Diphenhydramine: a potent antihistamine used as the hydrochloride salt in the treatment of allergic symptoms.

Etonogestrel/ethinyl estradiol ring is an estrogen/progestin combination. It works by preventing the release of eggs from the and thereby preventing pregnancy.

Flumazenil: is of benefit in patients who become excessively drowsy after benzodiazepines are used for either or procedures. It has been used as an antidote in the treatment of benzodiazepine overdoses.

Hepatitis B Hepatitis B is an infectious disease caused by the hepatitis B virus which affects the liver.

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A 000	Continued From page 2 Lo Loestrin Fe is a birth control pill with 10 micrograms of estrogen. Midazolam: marketed under the trade names Versed among others, is a medication used for anesthesia, procedural sedation, trouble sleeping, and severe agitation Morphine sulfate: Morphine is a narcotic pain reliever used to treat moderate to severe pain Product of conception: Obstetrics: The aggregate of tissues present in a fertilized gestation; in a pregnancy that has been terminated or aborted. Speculum : An instrument for dilating the opening of a cavity for medical examination Tuberculosis: commonly known as TB is a bacterial infection that can spread through the lymph nodes and bloodstream to any organ in your body.	A 000		
A 034	TAC 139.8(b)(1)(2)(3) Quality Assurance (b) QA committee membership. At a minimum, the QA committee shall consist of at least: (1) the medical consultant designated by the facility; (2) an advanced practice registered nurse, a physician assistant, a registered nurse, or a licensed vocational nurse; and (3) at least two other members of the facility's staff.	A 034	Medical Director shall be responsible for ensuring all required QA Committee staff attend the Quarterly meetings and will document their participation. This documentation will maintained in the QA manual.	11/23/15

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A 034	Continued From page 3 This Requirement is not met as evidenced by: Based on record review and interview, the facility's quality assurance committee failed to document that a licensed nurse and two other members of the facility's staff attended the facility's quarterly quality assurance meetings. Findings: Review of the facility's current policy on quality assurance revised 2012 direct staff as follows: " Purpose: Assurance of the delivery of quality patient care and to utilize opportunities to improve patient care by resolution of problems that involve medical care. The Patient Care Team assists with identifying problems and solving activities. It meets quarterly or more often if needed. This Team is comprised of the clinic administrator, nurse and the Medical Director. " Review on 10/06/2015 of the facility's quality assurance meeting minutes, dated March 2015 and June 2015 revealed no evidence that the licensed nurse and two other members of staff participated in the facility's quality assurance meeting. Review of the minutes, revealed the only signature on the minutes was that of the Facility's Medical Director. During an interview on 10/06/2015 at 1.35 p.m. the Surveyors reviewed the meeting minutes with the Facility's Medical Director and requested evidence that other staff members are involved in	A 034		

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A 034	Continued From page 4 the Facility's Quality Assurance Meeting. The Medical Director said he and his staff discuss the information but he had no evidence that they attended the meeting.	A 034		
A 036	TAC 139.8(d)(1)(2)(3)(4) Quality Assurance (d) Minimum responsibilities. The QA committee shall: (1) evaluate all organized services related to patient care, including services furnished by contract; (2) ensure that there is a review of any abortion procedure complication(s), and shall make use of the findings in the development and revision of facility policies; (3) address issues of unprofessional conduct by any member of the facility's staff (including contract staff); (4) monitor infection control as outlined in §139.49 of this title (relating to Infection Control Standards) and post-procedure infections as outlined in §139.41 of this title (relating to Policy Development and Review); This Requirement is not met as evidenced by: Based on record review and interview , the facility's quality assurance committee failed to monitor infection control practices in the facility Findings: Review of the Facility's current Policy on Quality Assurance, revised 2012 direct staff as follows: " Purpose: Assurance of the delivery of quality patient care and to utilize opportunities to improve patient care by resolution of problems that involve	A 036	Medical Director will be responsible for monitoring infection control practices in the facility. This will be monitored at least quarterly by the Medical Director and these reports will be reviewed by the QA committee as part of the facility's on going Quality Assurance Program.	11/23/15

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A 036	Continued From page 5 medical care. Goals: 1. To validate for the consumer that high quality care is being provided. 2. To identify and study problems from a variety of data sources , including : complication reports; infection control reports; patient surveys; staff physician and visitor complaints " Review on 10/06/2015 of the facility's quality assurance meeting minutes dated March 2015 and June 2015, revealed no evidence that the committee monitors Infection control in the facility. Interview with the Facility's Medical Director on 10/06/2015 at 1.35 p.m., during review of the quality assurance meeting minutes, the Surveyors informed him that there was no evidence that infection control practices were monitored in the facility. The Medical Director said he had no documented evidence that infection control practices were monitored in the facility.	A 036		
A 037	TAC 139.8(d)((5)(6)(7) Quality Assurance (d) Minimum responsibilities. The QA committee shall: (5) address medication therapy practices; (6) address the integrity of surgical instruments, medical equipment, and patient supplies; and (7) address services performed in the facility as they relate to appropriateness of diagnosis and treatment.	A 037	Medical Director will establish a facility policy for medication management and practices. This policy shall include proper handling and storage of medications as well as regular inspections of all medications to ensure no medications are expired. Medical Director will also conduct inspections to monitor medication practices as part of it's QA program and these reports will be reviewed by the Quality Assurance Committee.	11/23/15

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A 037	Continued From page 6 This Requirement is not met as evidenced by: Based on observation, record review and interview , the facility's quality assurance committee failed to monitor medication management/ practices in the facility Findings: Observation on 10/06/2015 at 10:00 a.m during tour of the facility revealed the following containers with medications were observed stored in an unlocked cupboard in the facility recovery area adjacent to the patient's bathroom: Seven containers of Ampicillin 500 mgs , 500 capsules per bottle; lot # 44382-4560, expiration date September 2017, Three bottles Ciprofloxin 500 mg, Lot # 5215015; Expiration date 12/2016. and multiple packets of physician samples of Lo Loestrin Fe. Observation 10/06/2015 at 1.40 p.m. revealed a single dose vial of Morphine Sulphate 1000 mg / 20 mls (lot # 42-413-DK was observed stored in a filing cabinet at the desk. Review of the label on the bottle revealed documention which indicated that the medication in the bottle was for single use only. During an interview with the Facility's Medical Director on 10/06/2015 at 1.40 p.m., the Facility's Medical Director said he opens a new bottle of morphine Sulfate 1000 mg/ 20 mls each month and uses it for multiple patients during procedures. The Surveyor informed the Facility's Medical	A 037		

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A 037	Continued From page 7 Director that the label on the Morphine Sulfate vial indicated that it was for single use only. The Facility's Medical Director stated " I did not know it was for single use only. When I ordered it I told them what I needed it for." Review of the Facility's Medication Administration Log provided by the Facility's Medical Director revealed documentation which indicated that multiple patients received 10 mgs doses of Morphine from the 1000 mg/ 20 mls vial. Review of the Manufacturer's insert for Morphine Sulfate injections direct users as follows : "Note This product is not intended for intrathecal or epidural use. It is for use after dilution, not for direct infusion and is intended for for single dose unit. It contains no antimicrobial preservatives. When the dosing requirement is completed , the unused portion should be discarded in an appropriate manner. " Review of the Facility's current Policy on Quality Assurance reviewed 2012 direct staff as follows: " Purpose: Assurance of the delivery of quality patient care and to utilize opportunities to improve patient care by resolution of problems that involve medical care. Goals: 1. To validate for the consumer that high quality care is being provided. 2. To identify and study problems from a variety of data sources , including : complication reports; infection control reports; patient surveys; staff physician and visitor complaints 3. To institute corrective action for problems	A 037		

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A 037	Continued From page 8 identified through on- going monitoring of activities. 4. To follow -up and document effectiveness of the action taken. 5. To reduce the number of potential compensable events relating to medical care. The Patient Care Team assists with identifying problems and solving activities. It meets quarterly or more often if needed. This Team is comprised of the clinic administrator, nurse and the Medical Director. " Review on 10/06/2015 of the facility's quality assurance meeting minutes dated March 2015 and June 2015, revealed no evidence that the committee monitors medication managent and practices in the facility. Interview with the Facility's Medical Director on 10/06/2015 at 1.35 p.m., during review of the quality assurance meeting minutes, the Surveyors informed him that there was no evidence that medication management /practices were monitored in the facility. The Medical Director said he had no documented evidence that medication management/ practices were monitored in the facility.	A 037		
A 147	TAC 139.44(a) Orientation/Training/Demonstrated Competency (a) A licensed abortion facility shall develop and implement a written orientation and training program to familiarize all employees (including office staff) with the facility's policies, philosophy, job responsibilities of all staff, and emergency	A 147	Medical Director will ensure staff orientation include training on the use of emergency equipment. Medical Director will conduct an in-service for staff and documentation will be placed in their personnel file.	11/2315

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A 147	Continued From page 9 procedures. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to provide training for Staff 1 (A) of 3 (A. B, and C) that could operate the emergency equipment. Staff "A" was asked to turn on the oxygen tank and then to turn on the suction equipment. Staff "A" was unable to turn on the oxygen tank. It was observed the oxygen tank was leaking oxygen around the gauge. Further observation of Staff "A" when tying to turn on the suction machine revealed she was unable to operate the patient suction machine. The suction tubing to the suction machine had expired in 2009. An interview with Staff "A" on 10/6/2015 at approximately 11:00 AM confirmed she did not know how to operate the oxygen and suction equipment if an emergency was to occur.	A 147		
A 159	TAC 139.45(3)(4)(5) Personnel Policies An individual personnel record shall be maintained on each person employed by the licensed abortion facility which shall include, but not be limited to, the following: (3) clinical laboratory tests results and vaccinations if required by law (e.g., Mycobacterium tuberculosis, hepatitis B virus); (4) documentation of the education, training, and experience of the employee, in addition to a copy or verification of the employee's current license or	A 159	Medical Director will ensure employees receive vaccinations for hepatitis B and TB. Documentation of laboratory test results or vaccinations will be placed in personnel file. Medical Director will also provide infection control training for all employees. Documentation of this training will be placed in personnel file.	12/1/15

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A 159	Continued From page 10 certification credentials, or both; and (5) documentation of the employee's orientation, in-service, and other educational programs provided by the licensed abortion facility (training), and employee evaluation. This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to provide laboratory testing and vaccinations to 3 (A, B, and C) of 3 staff members for Hepatitis B or Tuberculosis. Also, the facility failed to provide infection control training on 3 (A, B, and C) of 3 staff members. Findings: A review of the personnel records for Staff members A, B, and C revealed no laboratory testing and/or vaccinations for Hepatitis B or Tuberculosis. A review of the personnel records for Staff members A, B, and C revealed no infection control training. A review of the record titled, "Employee Annual Competency and Personnel Evaluation" revealed no infection control training. A review of the policy titled, "Women's Medical Center Administrative Policies" revealed the following: PERSONNEL *employees shall have job descriptions, orientation and on the job training. *inservices will be conducted twice a year at a minimum *personnel will be CPR certified	A 159		

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A 159	Continued From page 11 *personnel understand patient rights * will review clinic policies and procedures * staff are aware of reporting requirements for child abuse and neglect as well as family violence These records will be maintained and updated as necessary. Verification of license and certifications will be current and updated as needed. Job descriptions will be reviewed annually or more often if needed. Records will include documentation of orientation, in-service/training programs and evaluation. Test results for TB and Hepatitis B recorded in records. Administrator will maintain these records and this information is confidential and assessable only to authorized staff." An interview with Medical Director on 10/06/2015 at approximately 12:30 PM confirmed the above findings.	A 159		
A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to maintain a sanitary environment free of pooled blacked water in medication refrigerator,	A 197	Medical Director will establish cleaning policies for the facility. These policies will include staff and patient areas, refrigerator where medications are stored. These policies will also include proper storage of clean medical supplies and monthly inspection to ensure supplies are not expired. Medical Director will also be responsible for inspecting medical equipment to ensure it is maintained and in proper working order	12/1/15

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A 197	Continued From page 12 accumulation of dirt and dust in treatment area, expired medical supplies, rusty equipment and cluttered areas. Findings: Observation on 10/06/2015 at 8.30 a.m of the facility's examination room #2 revealed the following expired medical supplies were observed comingled with other supplies in use in the facility: The items were stored in a drawer below the examination table. Scalp vein set Lot # 060315 expired march 2011 Two safety blood collection set Luer adapter 21 g Lot # 69D01 expired March 2012 Two safety blood collection set Luer adapter Lot # 11G13 expired June 2014 Terumo injection needles 22 G x 1 1/2, 100 unit box , lot # WN1626 expired October 2003 Terumo injection needles 22 G x 1, 100 unit box , lot # AL0625 expired August 2006 4 Sterile scalp vein set 3.0 Lot # 060315 expired March 2011 5 Ethicon vicryl sutures 3.0 Lot # J332 expired July 2009 Observation on 10/06/2015 at 9.00 a.m of a refrigerator which stored medication, located in the facility's recovery area revealed the refrigerator had an accumulation of stagnant water with black residue in a tray located at the bottom of the refrigerator. Stored on the shelf above the pooled water were packets labeled Etonogestrel/ethinyl estradiol ring During an interview on 10/06/2015 at 11.20 a.m	A 197		

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A 197	Continued From page 13 with the Facility's Medical Director the Surveyor notified him of the pooled black water in the bottom tray of the refrigerator. The Medical Director said the facility staff were responsible for cleaning the refrigerator. Observation on 10/06/2015 AT 11.48 a.m revealed a bottle of ultrasound gel, Lot # N 12217143 was observed stored in the sterilization room. The label on the bottle indicated an expiration date of May 2015 During an interview on 10/06/2015 at 11.49 a.m with the Medical Assistant responsible for doing ultrasounds on patients, the Surveyor asked the Medical Assistant if the bottle of ultra sound jell was in use in the facility. The Medical Assistant said the expired ultrasound jell was currently in use and that it was the only bottle of jell available in the facility. Observation of a cupboard in the sterilization area of the facility revealed a box of injection needles (100) units , Lot # LK2626 was observed stored in the cupboard. The expiration date on the box of needles was dated July 2014. During a tour of the Ultrasound exam room on 10/06/2015 at 9:00 AM, the following expired items were observed: Intravenous Fluids of Normal Saline 1000 cc X 9 expiration date of 2006 and 2007 Safety Blood Collection Set X 1 expiration date of 6-2014 Safety Blood Collection Set X 7 expiration date of 10-2015 Sure Path (Pap test) X 50 expiration date of 10-2014	A 197		

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A 197	Continued From page 14 Band aides Box of 100 expiration date of 3-2014 Vitro Diagnostic X 8 expiration date of 4-21-2014 Vitro Diagnostic X 10 expiration date of 6-21-2014 Endocervical Swab X 10 expiration date of 7-31-2015 Endocervical Swab X 9 expiration date of 2-28-2015 Gray top blood tube X 1 expiration date of 9-2013 Culture and sensitivity transfer straw kit expiration date of 6-2014 Numerous Suture packets with expiration dates of 1-1995, 7-1997, 7-1995 Three boxes of needles with expiration dates of 2006, 2008, and 2009. Observed in the Emergency Medical Kit, the following Medications were expired: Flumazenil 15 mg X 2 expiration date of 7-2015 Midazolam X 1 expiration date of 10-1-2015 Diphenhydramine 50 mg X 1 expiration date of 7-1-2015 Ultrasound Exam room: The room was cluttered with a broken lamp pole, 2 broken ultrasound machines, oxygen tank covered in dust with the nasal cannula hanging from the tank, and a rolling cart with 4 outside shipping cardboard boxes. All the equipment in the ultrasound room was covered in dust. The cabinet below the hand washing sink in the ultrasound room was filled with supplies rolls of exam table paper, gloves, Kleenex, and disposable vaginal speculums. Exam Room #2 and #3 During the tour, it was observed that patient blue pads were being stored on the floor of the exam rooms. Syringes were observed on the mayo stand that was set up for patient procedures and in the drawer of the exam table. The syringes were filled with a clear liquid with no label, date, time, and to	A 197		

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A 197	Continued From page 15 who had filled the syringes. The suction machine being used for the procedure was discolored and the face was covered in rust. (Rust cannot be cleaned to prevent infectious contaminate.) A handmade tongue blade was in the drawer under the exam table. The silk tape wrapped around the wooden tongue blade was yellow in color and the tape was coming undone from the tongue blade. Sterilization Area There were numerous outside shipping card board boxes stacked beside the washer and dryer. There were instruments on the shelves opened and unwrapped, but not labeled to know if the instruments were clean or dirty.	A 197		
A 198	TAC 139.48(1)(B) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (B) equip each procedure room so that procedures can be performed in a manner that assures the physical safety of all individuals in the area; This Requirement is not met as evidenced by: Based on observation and record review, the facility failed to have equipment in the ultrasound exam room that was in working condition. Findings: During a tour of the ultrasound room on 10/06/2015 revealed 3 ultrasound machines were observed in the room. Two of the three machines were not in working condition and there	A 198	Medical Director will establish a policy for non functioning equipment to include signage to alert all staff. Functioning medical equipment will have annual preventative maintenance stickers to notify staff.	11/23/15

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A 198	Continued From page 16 were no preventive maintenance stickers informing the staff the machines were safe to use on a patient. The machines were covered in dust particles. One of the ultrasound machines vaginal probe tip was cracked and a black substance was observed on the inside of the vaginal probe tip. There were no signage to inform the staff members that the ultrasound machines were broken and do not not use for patient care. An interview with the Staff C (Ultrasound Technician) on 10/06/2015 at 9:30 AM confirmed the above findings. An interview with the Medical Director on 10/06/2015 at 12:30 PM confirmed the above findings.	A 198		
A 200	TAC 0139.48(1)(D) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (D) have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's emergency evacuation protocol required by this subparagraph; This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to have a fire extinguisher mounted on the wall and available for use.	A 200	Medical Director will be responsible for ensuring a fire extinguisher is mounted on wall and available for use. All staff will be instructed on location and proper use.	11/23/15

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A 200	Continued From page 17 Findings: During a tour of the facility on 10/06/2015 the fire extinguisher was sitting in the recover area on the floor. Staff A was asked do you know how to work the fire extinguisher. Staff A stated, "No not really." An interview with Staff #A on 10/06/2015 at approximately 10:30 AM confirmed the above findings.	A 200		
A 211	TAC 139.49(b)(1) Infection Control Standards (b) Prevention and control of the transmission of HIV, HBV, HCV, TB, and S. spp. (1) Universal/standard precautions. This Requirement is not met as evidenced by: Based on observation, interview and record review, the facility failed to implement polices to ensure staff who had direct contact with patients were tested for tuberculosis and Hepatitis B in 3 of 3 staff observed and Personnel records reviewed. Staff A B and C Findings On 10/06/2015 staff (A, B and C) were observed working in the facility and interacting with patients. Interview on 10/06/2015 at 12.08 p.m. with the Facility's Medical Director, the Surveyors	A 211	Medical Director will ensure employees receive vaccinations for hepatitis B and TB. Documentation of laboratory test results or vaccinations will be placed in personnel file. Medical Director will also provide infection control training for all employees. Documentation of this training will be placed in personnel file.	12/1/15

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A 211	Continued From page 18 requested evidence that staff were tested for Tuberculosis and Hepatitis B. The Facility's Medical Director stated " Is it in the rules." The Medical Director said he did not know that facility's staff needed to have tuberculosis and Hepatitis (B) testing. A review of the policy titled, "Women's Medical Center Administrative Policies" revealed the following: PERSONNEL Test results for TB and Hepatitis B recorded in records. Administrator will maintain these records and this information is confidential and assessable only to authorized staff." Review of Staff A, B and C's personnel record revealed no policy implemented for Tuberculosis testing of staff,	A 211		
A 217	TAC 139.49(b)(3)(A)(B)(C)(D) Infection Control Standards (3) Educational course work and training. A licensed abortion facility shall require its health care workers to complete educational course work or training in infection control and barrier precautions, including basic concepts of disease transmission, scientifically accepted principles and practices for infection control and engineering and work practice controls. To fulfill the requirements of this paragraph, course work and training may include formal education courses or in-house training or workshops provided by the facility. The course work and	A 217	Medical Director will ensure all staff recieves infection control training. Documentation of this training will be placed in personnel file.	12/1/15

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A 217	Continued From page 19 training shall include, but not be limited to: (A) HIV infection prevention; and (B) HBV, HCV, TB, and S. spp. infection prevention based on universal/standard precautions as defined in paragraph (1) of this subsection; (C) bidirectional aspect of disease transmission; and (D) epidemic control. This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to provide infection control training on 3 (A, B, and C) of 3 staff members. Findings: A review of the personnel records for Staff members A, B, and C revealed no infection control training. A review of the record titled, "Employee Annual Competency and Personnel Evaluation" revealed no infection control training. A review of the policy titled, "Women's Medical Center Administrative Policies" revealed the following: PERSONNEL *employees shall have job descriptions, orientation and on the job training. *inservices will be conducted twice a year at a minimum *personnel will be CPR certified *personnel understand patient rights * will review clinic policies and procedures	A 217		

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A 217	Continued From page 20 * staff are aware of reporting requirements for child abuse and neglect as well as family violence These records will be maintained and updated as necessary. Verification of license and certifications will be current and updated as needed. Job descriptions will be reviewed annually or more often if needed. Records will include documentation of orientation, in-service/training programs and evaluation. Test results for TB and Hepatitis B recorded in records. Administrator will maintain these records and this information is confidential and assessable only to authorized staff." An interview with Medical Director on 10/06/2015 at approximately 12:30 PM confirmed the above findings.	A 217		
A 226	TAC 139.49(d)(3)(A) Infection Control Standards (3) Inspection of surgical instruments. (A) All instruments shall undergo inspection before being packaged for reuse or storage. Routine inspection of instruments shall be made to assure clean locks, crevices, and serrations. This Requirement is not met as evidenced by: Based on observation , and record review, the facility failed to maintain sterilized equipment/ instruments sealed in packages in 1 of 3 procedure rooms observed Findings Observation on 10/08/2015 at 9.30 a.m in	A 226	Medical Director will develop policy regarding inspection of instruments before being packaged and of sterile instruments in sealed packages. These policies will also address proper labeling and storage. Medical Director will in-service staff on these policies. Random inspections will be conducted as part of the facility's on-going Quality Assurance Program.	12/1/15

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A 226	Continued From page 21 procedure room #3 revealed the following instruments were observed stored in self sealed sterilization pouches in drawers below the examination table. 1 metal speculum not dated when sterilized and the seal was broken 1 metal curette enclosed in a Henry Shein self sterilization pouch. The seal was broken and there was no date on the packet as to when it was sterilized. 1 metal forceps enclosed in a self seal sterilization packet dated 03/09/2017. The packet had brown water stain marking on it. 1 metal sponge forceps enclosed in a self sealing pouch taped at both ends. There was no date on the packet as to when it was sterilized. 9 instruments in self sealed pouches which were not completely sealed. On 10/06/2015 at 9.10 a.m the Surveyor notified the facility's Licensed Vocational Nurse of their observation. The Licensed Vocational Nurse said she would take care of the expired supplies.	A 226		
A 242	TAC 139.49(d)(5)(D)(i)(ii) Infection Control Standards D) Packaging. (i) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall not exceed 17 pounds.	A 242	Medical Director will develop policy regarding inspection of instruments before being packaged and of sterile instruments in sealed packages. These policies will also address proper labeling and storage. Medical Director will in-service staff on these policies. Random inspections will be conducted as part of the facility's on-going Quality Assurance Program.	12/1/15

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A 242	Continued From page 22 (ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to label peel packs and wrapped instruments with date and load number. Findings: During a tour of the facility on 10/06/2015 revealed multiple peel pack packages and wrapped instruments were not dated or labeled with the load number. Approximately 20 peel packs were crushed in the drawer beneath the exam table. Also, the peel packs had water stains on them. An interview with Staff #A on 10/06/2015 at approximately 11:00 AM confirmed the above findings. Observation on 10/06/2015 at at 09:30 a.m of examination room number three revealed the following instruments were observed stored in the drawers below the examination tables. The Instruments were not labeled with the date and time they were sterilized: I metal Curette enclosed in a self sealing sterilization pouch. 1 metal speculum enclosed in a self sealing sterilizing pouch 1 metal sponge forceps taped on both ends of the self sealing pouch.	A 242		

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A 244	Continued From page 23	A 244		
A 244	TAC 139.49(d)(5)(F)(i)(ii) Infection Control Standards (F) Biological indicators. (i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used (e.g., Bacillus stearothermophilus for steam sterilizers). (ii) Biological indicators shall be included in at least one run each day of use for steam sterilizers. This Requirement is not met as evidenced by: Based on observation, record review, and interview the facility failed to perform biological testing for the bacterial growth and possible sterilization failure. Findings: Observation on 10/06/2015 at 11.10 a.m of the sterilization area revealed a sterilizer was observed in the facility. A review of the biological log revealed there was no biological log. There was no readings documented after 48 hours to know if the biological had any bacterial growth and possible sterilization failure. A review of the record titled, "policy for testing Biological Indicator" reveled the following: "POLICY FOR ATEST BIOLOGICAL INDICATOR WITH FIRST LOAD Of DAY 1. PLACE ATEST CONTROL INTO INCUBATOR	A 244	Medical Director will ensure Biological Indicators will be run on sterilizer according to instructions. Documentation of tests results will be maintained. In-service training will be provided to staff working in sterilization. Documentation of this training will be placed in personnel files.	12/1/15

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A 244	Continued From page 24 LABELED CONTROL & DATED. 2. 5 MIN. AFTER AUTOCLAVE IS DONE REMOVE ATEST FROM LOAD SET SIDE FOR 10 MIN. OR UNTIL COOLED TO ROOM TEMP. 3. CRUSH ATEST INDICATOR 4. PLACE DATED ATEST INDICATOR INTO INCUBATOR 5. AFTER 24 HOURS DOCUMENT RESULTS OF INDICATOR 6. AFTER 48 HOURS DOCUMENT FINAL RESULT 7. IF RESULTS ARE POSITIVE WITH GROWTH NOTIFY MEDICAL DIRECTOR IMMEDIATELY. 8. ONCE ALL RESULTS ARE DOCUMENTED DISCARD ATEST INDICATORS." An interview with the Medical Director on 10/06/2015 at approximately 12:30 PM revealed he did not understand the policy for the biological testing.	A 244		
A 245	TAC 139.49(d)(5)(F)(iii)(iv)(v) Infection Control Standards (F) Biological indicators. (iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load. (iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations. (v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A	A 245	Medical Director will ensure Biological Indicators will be run on sterilizer according to instructions. Documentation of tests results will be maintained. In-service training will be provided to staff working in sterilization. Documentation of this training will be placed in personnel files.	12/1/15

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A 245	Continued From page 25 list of all items which were used after the last negative biological indicator test shall be submitted to the administrator. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to perform biological testing for the bacterial growth and possible sterilization failure and document the results on a log for 1 of 1 sterilizer in use in the facility. Findings: Observation on 10/06/2015 at 11.10 a.m of the sterilization area revealed a sterilizer was observed in the facility. A review of the biological log revealed there was no readings documented after 48 hours to know if the biological had any bacterial growth and possible sterilization failure. A review of the record titled, "policy for testing Biological Indicator" reveled the following: "POLICY FOR ATEST BIOLOGICAL INDICATOR WITH FIRST LOAD Of DAY 1. PLACE ATEST CONTROL INTO INCUBATOR LABELED CONTROL & DATED. 2. 5 MIN. AFTER AUTOCLAVE IS DONE REMOVE ATEST FROM LOAD SET SIDE FOR 10 MIN. OR UNTIL COOLED TO ROOM TEMP,	A 245		

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A 245	Continued From page 26 3. CRUSH ATEST INDICATOR 4. PLACE DATED ATEST INDICATOR INTO INCUBATOR 5. AFTER 24 HOURS DOCUMENT RESULTS OF INDICATOR 6. AFTER 48 HOURS DOCUMENT FINAL RESULT 7. IF RESULTS ARE POSITIVE WITH GROWTH NOTIFY MEDICAL DIRECTOR IMMEDIATELY. 8. ONCE ALL RESULTS ARE DOCUMENTED DISCARD ATEST INDICATORS." An interview with the Medical Director on 10/06/2015 at approximately 12:30 PM revealed he did not understand the policy for the biological testing.	A 245		
A 249	TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall ensure proper storage and handling of items in a manner that does not compromise the packaging of the product. (i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage. (ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity. (iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised. (iv) Storage of supplies shall be in areas that are designated for storage.	A 249	Medical Director shall establish policies for the storage of sterilized items to ensure proper handling that does not compromise packaging. These policies will address proper positioning to prevent crushing,bending, compressing or puncturing that would compromise sterility.	12/1/15

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A 249	Continued From page 27 This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to store peel packs instruments in a position that was free of being crushed, bent, compressed, or punctured. FINDINGS; During a tour of the facility on 10/06/2015 , multiple peel pack packages were stored in a drawer beneath the exam table. Approximately 20 peel packs were crushed and compressed in the drawer beneath the exam table. Also, the peel packs had water stains on them. The facility had no area designated for storage for sterile peel packs. An interview with Staff #A on 10/06/2015 at approximately 11:00 AM confirmed the above findings.	A 249		
A 334	[redacted]	A 334	[redacted]	11/23/15

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A 334	Continued From page 28 [redacted]	A 334		