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
	007326	A. BUILDING: _____ B. WING _____	08/16/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOUSTON WOMENS CLINIC	4820 SAN JACINTO HOUSTON, TX 77004

(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 re-licensure survey was conducted per Title 25 TAC Chapter 139 Abortion Facility Reporting and Licensing Rules to determine the facility's compliance with the requirements. An entrance conference was conducted on August 16, 2016 at 9:45 AM with the Charge Nurse. An opportunity was provided for questions and discussion. An exit conference was conducted on August 16, 2016 at 5:00 PM with the Charge Nurse and the Consultant for the Clinic. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for facility to provide evidence of compliance with those requirements for which non-compliance had been found. Deficiencies were cited. Photographic evidence obtained:	A 000	Received SEP 16 2016 HFC Zone V REVIEWED SEP 16 2016 by: Lea Ann Howell, RN RB	
A 035	[redacted]	A 035		

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LABORAT

TITLE: MEDICAL DIRECTOR — (X6) DATE: 9-16-16

STATE F

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A 035	Continued From page 1 [redacted]	A 035	[redacted]	

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A 130	Continued From page 3	A 130		
A 130	TAC 139.41(a)(2)(G)(H)(I) Policy Development and Review (G) clinical records; (H) reporting and filing requirements; and (I) monitoring post-procedure infection(s). This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to develop, implement, and monitor clinical policies regarding post procedure patient follow-up and monitoring of post-procedure infections for 11 of 11 patients reviewed (#1- #11). Findings include: Review of 11 sampled patients clinical records revealed no evidence of post procedure follow-up attempts. Record review of the facility's complication call logs revealed information was only available for the time period encompassing 7-27-16 to 8-15-16. There was no information available prior to that time period. Record review of the facility's policies and procedures on 8/16/16, revealed no evidence that the facility had developed/ implemented policies relating to post procedure patient follow-up and monitoring of post-procedure infections. In an Interview conducted on 8-16-16 at 3:15 p.m., the facility Consultant and Charge nurse both confirmed the above findings. The Consultant revealed that the facility does not have a policy/ process for patient post procedure	A 130	Facility policy for routine follow-up is included in post operative instructions (see attachment # 4) These instruction are given to every patient verbally and in writing Nursing Supervisor shall develop a policy and a call log for documentation of patient calls reporting possible post-abortion complications to include Fever, pain or heavy bleeding. This log shall remain in Facility. All nursing staff will be advised of these policies ~~QA committee~~	10.30.16

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A 130	Continued From page 4 follow-up. In regards to the monitoring of complications, the Consultant further stated that the previous Charge Nurse had failed to leave the previous complication call log with the facility when she left employment. As a result, the facility has no record of calls/complications before the current period.	A 130	Quality Assurance committee will review call complication log as part of facility's on-going QA.	
A 143	TAC 139.43(2)(3)(4)(5) Personnel Policies (2) a requirement for orientation of all employees, volunteers, students and contractors to the policies and objectives of the facility and participation by all personnel in employee training specific to their job; (3) job-related training for each position; (4) a requirement for an annual evaluation of employee performance; (5) in-service and continuing education requirements; This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to conduct annual evaluations and infection control training on 6 (#1, #7, #9, #15, #20, and #21) of 8 (#1, #5, #7, #9, #11, #15, #20, and #21) of staff files reviewed. Also, the facility failed to follow their own policy. A record review of Staff #9's file revealed the last performance evaluation was written June 2013. Further review of the Staff #9's file revealed no documented infection control training. A review of Staff (#1, #7, #15, #20, and #21) files revealed no annual evaluation conducted in the last year nor was there any infection control	A 143	Nursing supervisor is responsible for ensuring all staff Recieves infection control training. This training will be performed by nursing Supervisor. Administrator will ensure annual evaluations are conducted on all employees Administrator wal develop a check list for each employee file to ensure staff files are Current, with training 2x year	10.30.16 10.30.16 10.30.16

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A 143	Continued From page 5 training documented in their personnel file. A review of the policy titled, "Administrative Policies" revealed the following: 1. Personnel: Employees shall have job descriptions, orientation and on the job training Annual evaluations will be conducted to assess staff competency In-services will be conducted twice a year at a minimum etc." An interview with the Consultant and Charge Nurse on 08/16/2016 at 2:00 PM confirmed the above findings and that the facility's policy was not followed.	A 143	QA committee will conduct random review of staff files to ensure training is current and Facility is in compliance	
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 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.	A 159	Nursing Supervisor will be Responible for Reviewing all employee files to ensure TB, Hep B vaccination and/or titers are current	10.30.16

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A 159	Continued From page 6 This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to ensure that laboratory testing and vaccinations were conducted/provided for 5 of 21 employees (#1, #7, #15, #20, and #21) reviewed. The facility failed to ensure that records were maintained showing that Hepatitis B titers were drawn and/or vaccinations were given, and that Tuberculosis testing was conducted for employees. Findings included: A review of the personnel records for employees #1, #7, #15, #20, and #21 revealed no laboratory testing and/or vaccinations for Hepatitis B or Tuberculosis. In an interview conducted on 8/16/16 at 2:10 PM, the Charge Nurse and facility Consultant both confirmed the above findings. When asked by the surveyor for the facility's policy regarding employee vaccinations, the Charge Nurse stated that the facility did not have one.	A 159	Nursing supervisor will develop facility policy For employee vaccinations. This policy will be included in facility policy and procedure Manual QA committee will conduct random review of staff files to ensure records are current and facility is in compliance.	10.30/16 10.30/16
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;	A 197		

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A 197	Continued From page 7 This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to provide a clean and sanitary environment to protect the health and safety of patients and minimize the transmission of infections. Findings: During a tour of the facility on 08/16/2016 from 10:00 AM through 11:00 AM the following infection control and safety issues were observed: 1. The facility was using the sterilization storage area to store cardboard shipping boxes. The boxes were stored directly on the floor and stacked 4 feet high. 2. The AED (automatic defibrillator device) was stored on the second shelf in the sterilization storage area with a plastic container full of emergency supplies. If a patient emergency occurred, the cardboard boxes were blocking the availability for the staff to reach the emergency equipment. 3. Multiple old yellowish phone books were being stacked on the first shelf in the sterilization room and stacked beside the phone books were peel pouches of sterile instruments. 4. It was observed in the peel pouches that contained sterile instruments that the external chemical indicators were not being used. Due to the indicator missing from the package there was no way to know if the items had been exposed to the sterilization process.	A 197	Administrator will develop policies to ensure sterilization area is clean and clear of cardboard shipping boxes. Policy will also ensure AED (auto defibrillator device) is easily accessible. All staff working in sterilization area will be advised of policy regarding sterilization area. QA Committee will conduct random inspections to ensure compliance Peel Pouches have external chemical indicator strips in each of the packs. (See attachment #5)	10.20.16

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A 197	Continued From page 8 5. Observed during the tour that peel pouches X 9 were loaded in the sterilizer. The pouches were stacked on top of peel pouches which was not recommended by the sterilizer manufacturer (Ritter M 11 UltraClave). 6. Patient supplies were being stored under the sink. Observed a 2 x 4 water stain under this sink where patient supplies were stored. 7. Found 24 pre-filled syringes which were unlabeled/undated were being stored in an unlocked cabinet underneath the surgical suction machine. The Charge Nurse revealed that two (2) of the syringes contained Valium, One (1) contained Stadol, One (1) contained Romazicon, and the other Twenty (20) contained Chloroprocaine. 8. In exam room #1 cardboard boxes were being stored behind the exam tables and on top of the cardboard boxes were patient blue pads. These patient supplies were being exposed to infectious contaminates from the shipping cardboard boxes and likelihood of waste from the procedure. 9. In exam room #1 cardboard boxes were being stored under the counter directly on the floor. The cardboard boxes were only 2 feet from the patient exam table where the procedure is performed. 10. In exam room #1 under the sink observed a staff members purse, patient supplies, books, hydrogen peroxide, and cleaning supplies. 11. In exam room #2 patient supplies were being	A 197	Nursing Supervisor shall develop sterilization policies for facility and conduct in-service training for all staff working in sterilization area. 10.30.16 nursing supervisor shall develop policy for storage of pre-filled syringes to include date and labeling of contents. All medical staff will be trained on policy. 10.30.16 QA committee will conduct random inspections to ensure facility is in compliance Administrator will develop facility policy for storage of patient supplies, to include beverages for patients, laundry supplies and supplies in exam rooms 10.30.16	

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A 197	Continued From page 9 stored under the sink. Paper towels, comet, Lysol, cleaning detergent, Santi-wipes, and body wipes were all stored under the sink.	A 197		
	12. The vinyl recliner chairs in the recovery area had foam stuffing coming out of the chairs. The condition of the chairs had the likelihood to expose patients to infectious waste, due not to being able to clean the chairs.		Administrator shall be responsible for replacing recliner chairs in recovery area that have tears in vinyl.	11.30.16
	13. The water that was provided to patients was being stored directly on the floor behind one of the patient's recovery room chairs. Also, the soiled laundry bag stand containing soiled linen was sitting beside the patient water.			
	14. The intravenous stands and laundry stands had corrosive rust spots.		Nursing Supervisor shall be Responsible for Replacing I.V. Stands with Rust Spots	11.30.16
	15. In the kitchen area, which was off the recovery area, patient supplies were being stored in the kitchen cabinet under the kitchen counter. Observed box of syringes, two boxes of sterile alcohol pads, blue pads, three packages body wipes, and a box of surgical tape.		Administrator shall be Responsible for developing policy on Storage of patient Supplies, patient liquid nutrition, and cleaning Supplies.	10.30.16
	16. Patient's liquid nutrition that was provided to the patients was being stored directly on the floor in the kitchen area.			
	17. Two cases of chips and cookies were being stored on top of the Kitchen refrigerator. Patient and staff food supplies were mixed together in the refrigerator. The temperature of the patient's		QA committe will conduct random inspections to ensure compliance.	

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A 197	Continued From page 10 nutrition was not being monitored. 18. A gallon of bleach, bottle of cleaning detergent, suction canister, sharps container, and some type of filter hanging from the drain pipe were observed under the kitchen sink. 19. In the sonogram room, observed patient supplies stored under the sink. Rolls of exam table paper x 6, body wipes x 8 packages, soap, lotion, and Lysol spray were all being stored under the sink. 20. In the sonogram room closet, observed dust and dirt particles on the floor under the extra suction machine. 21. In the sonogram room behind the exam table, cardboard boxes were stored. Observed that two of the boxes were open and patient supplies being used out of the open boxes. 22. During the tour of the facility, observed the ceiling tiles were yellow in color and multiple spots of water leakage. An interview with the Consultant and Charge Nurse on 08/16/2016 at 11:00 AM confirmed the above findings.	A 197	Administrator shall develop policy for cleaning of exam rooms, including sonogram room. Staff will be advised of policy. QA committee will conduct random inspections to ensure compliance. Administrator had ceiling tiles replaced where yellowing and water spots were identified.	10.30.16 8.18.16
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	A 200		

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A 200	Continued From page 11 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, record review, and interview, the facility failed to conduct monthly checks for 3 of 3 fire extinguishers in the facility according to the National Fire Protection Association (NFPA) 10, Standard for Portable Fire Extinguishers. Also, the facility failed to conduct quarterly fire drills for 4 of 4 quarters of the year 2015-2016 to demonstrate the staff role and responsibility to implement the facility's emergency evacuation. A review of the NFPA 10 standards for portable fire Extinguishers revealed the following: "7.2.4.3 At least monthly where manual inspections are conducted, the date the manual inspection was performed and the initials of the person performing the inspection shall be recorded. 7.2.4.4 Where manual inspections are conducted, records for manual inspections shall be kept on a tag or label attached to the fire extinguisher, on an inspection checklist maintained on file, or by an electronic method. 7.2.4.5 Records shall be kept to demonstrate at least the last 12 monthly inspections have been performed." During the tour of the facility, 3 fire extinguishers	A 200	Administrator shall develop policy for monthly checks of 3 of 3 fire extinguishers in facility. This policy will include date and ititials of staff person performing monthly inspections. Administrator will ensure fire drills are conducted quarterly. Administrator shall develop Facility policy for quarterly fire drills.	10.30.16 10.30.16

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A 200	Continued From page 12 were observed that were not checked and initialed to know if the extinguishers were being maintained on a monthly basis. The staff would not know if a fire extinguisher was in its designated place, that it had not been actuated or tampered with, and that there was no obvious physical damage or condition to prevent its operation. A review of the fire drill documentation revealed that the facility had never conducted fire drills in the facility. An interview with Staff #6 on 08/16/2016 at 11:00 AM confirmed the above observations and findings.	A 200		
A 210	TAC 139.49(a) Infection Control Standards (a) Written policies. A licensed abortion facility shall develop, implement, and enforce infection control policies and procedures to minimize the transmission of post-procedure infections. These policies shall include, but not be limited to, the prevention of the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Mycobacterium tuberculosis (TB), and Streptococcus species (S. spp.); educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies. This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to enforce infection control policies to minimize the transmission of infection. The facility failed to:	A 210		

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A 210	Continued From page 13 * Ensure Syringes of injectable medications were labeled, initialed and dated when drawn. * Ensure expired suction catheters were removed from patient use. * Ensure cleaning equipment/implements were not stored in cabinets where supplies/ medications were kept, and * Remove shipping boxes from areas where supplies designated for patient use were stored and/or medical procedures were preformed. This deficient practice placed all patients receiving treatment in the facility at an increased risk of significant health problems and infections. Findings include: Observation during initial tour of the facility on 09/23/15 between 8:45 a.m. & 9:30 a.m. revealed the following: Procedure Room # 1: * A mop head used for cleaning the floors was being stored inside a cabinet underneath the medical suction machine. * Shipping boxes containing supplies were stacked up approximately 3-4 feet behind the procedure/exam table. Procedure Room # 2: * Seventeen (17) syringes of pre- drawn Nescaine 2%, were not labeled, initialed, and/or	A 210	Administrator shall develop facility policy for storage of patient supplies, clean supplies to include removing cardboard shipping boxes from exam rooms. Administrator will develop policy for inspection of supplies to check for expired supplies. Nursing supervisor will develop policy for labeling of pre-drawn Syringes All staff will be advised of above policies and QA committee will conduct random inspections to ensure compliance	10.30.16

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A 210	Continued From page 14 dated, and were being stored in the cabinet underneath the surgical suction machine. Procedure Room # 3: * Twenty Four (24) pre-filled syringes, (2 Valium, 1 Stadol, 1 Romazicon, and 20 Nescaine 2%) were not labeled, initialed and/or dated, and were being stored in the cabinet underneath the surgical suction machine. *Eleven (11) suction catheters (Curettes) used for procedures were expired. Expiration dates ranged from 2/2010 to 3/2015. * Five (5) red top laboratory tubes used for blood samples expired on 7/2015. In an interview at time of observation, the Charge Nurse confirmed the above findings, stating that staff should be checking for expired supplies daily when re-stocking. She further confirmed that syringes containing medications should be labeled/dated at the time they are drawn- up.	A 210		
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	A 242		

Texas Department of State Health Services

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A 242	Continued From page 15 instrument trays shall not exceed 17 pounds. (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 document on the instrument packages the following: the date and time of sterilizing, sterilizing load number, and the identification of the autoclave used. Observed during the tour of the sterilization room on 08/16/2016 at approximately 10:04 AM the peel pouches in the plastic container and the peel pouches that were being removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and the identification of the autoclave used. Also, observed that the peel pouches were not sealed on the perforated line; which was indicated on the peel pouches by the manufacturer. This type of packaging left an open seal and the sterile instrument would not be considered sterile. An interview with the Staff #6 on 08/16/2016 at 11:00 AM confirmed the above findings.	A 242	Documentation on instrument packages includes date, sterilizing load number and identification of autoclave used. (See attachment #6) Documentation of loads and times can be found on sterilization log (See attachment #7) Nursing Supervisor will review policy with all staff working sterilization to ensure compliance Nursing Supervisor will also conduct inservice on proper sealing of peel pouches	10/30/16
A 243	TAC 139.49(d)(5)(E)(i)(ii) Infection Control Standards (E) External chemical indicators. (i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have	A 243		

Texas Department of State Health Services

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A 243	Continued From page 16 been exposed to the sterilization process. (ii) The indicator results shall be interpreted according to the manufacturer's written instructions and indicator reaction specifications. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to use external chemical indicators in the peel pouches and failed to follow the policy. During the tour of the sterilization room on 08/16/2016 at approximately 10:04 AM, observed peel pouches that were being stored in a plastic container and the peel pouches that were being removed from the autoclave, did not have chemical indicators. A review of the record titled, "Infection Control" revealed the following: "E. Sterilization indicators will be used with each package and interpreted according to manufacturer's instructions." "Chemical indicators are defined by the Association for the Advancement of Medical Instrumentation (AAMI) as "...sterilization process monitoring devices designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. CIs are often used to detect sterilizer malfunction/failures resulting from improper loading of the sterilizer, incorrect packaging, deficiencies of the sterilizing agent, or malfunction of the sterilizer itself. " An interview with the Staff #6 on 08/16/2016 at 11:00 AM confirmed the above findings and that	A 243	Nursing Supervisor will inservice all staff working in sterilization to ensure sterilization indicators are used with each package. QA committee conducted an inspection of peel pouches and found all packages to contain external sterilization indicators (See attachment #8) QA committe will conduct on-going Random inspections to ensure facility compliance	10.30.16

Texas Department of State Health Services

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A 243	Continued From page 17 the facility policy was not being followed.	A 243		
A 246	TAC 149.49(d)(5)(G)(i)(ii) Infection Control Standards (G) Sterilizers. (i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions. (ii) Other sterilizers shall be used in accordance with the manufacturer's instructions. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to follow the manufacturer instructions for the Ritter M11 UltraClave (Sterilizer) for loading peel pouches. During the tour of the sterilization room on 08/16/2016 at approximately 10:04 AM, observed 9 peel pouches that were stacked on top of other peel pouches in the sterilizer. Observed both sterilizers were packed with peel pouches stacked on top of other peel pouches. According to the Ritter M11 UltraClave manufacturer guidelines, peel pouches must be in a tray and edges can only touch. Peel pouches may not be stacked on top of each other. Never overload or crowd the chamber. Do not let material come in contact with the door or sides of chamber. Separate packs into separate loads. An interview with the Staff #6 on 08/16/2016 at	A 246	Nursing Supervisor shall develop policy for sterilization to include proper load amounts in accordance with manufacturers instructions. Nursing Supervisor shall provide training to all staff working in facility Sterilization area. 10/30/16 Q.A. committe shall conduct random inspections of sterilization area to ensure compliance	

Texas Department of State Health Services

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A 246	Continued From page 18 10:04 AM confirmed the above findings and that the manufacturer instructions for the Ritter M11 UltraClave were not being followed.	A 246		
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. This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to store peel pouches in a position that was free of being crushed, bent, compressed, or punctured. FINDINGS: During a tour of the facility on 08/16/2016 at 10:00 AM multiple peel pouches were stored directly on the wooden shelf and others were packed tightly in plastic container in the sterilization/storage room.	A 249	Nursing Supervisor shall develop policies for storage of sterile supplies to ensure proper storage so that their sterility is not compromised Nursing supervisor shall designate location for sterile supplies to be stored All Staff working in sterilization will be instructed by nursing supervisor QA. Committe shall conduct random inspection to ensure on-going compliance.	10-30-16

Texas Department of State Health Services

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A 249	Continued From page 19 Multiple peel pouches were crushed and compressed in the plastic container which had no lid and was stored in the sterilization/storage room. The doorway to the pathology room where products of conception were examined and contaminated instruments were washed was beside the sterilization/storage room area. There was no door to close to prevent the sterile items from being exposed to infectious contaminate. Also, the sterilization area was where the facility was storing cardboard shipping boxes from the outside. The facility had no designated area for the storage of sterilized instruments. Also, sterilized instruments were observed on an open small wooden shelf in the main hallway in front of the exam rooms where the main traffic of the facility takes place. A review of documents revealed no temperature and humidity being recorded to know if instruments were being stored in a well ventilated limited access area. An interview with Staff #1 and #6 on 08/16/2016 at approximately 10:00 AM confirmed the above findings.	A 249	Nursing Supervisor will ensure temperature and humidity is recored on a log. Sterilization staff will be advised to record. QA ommittee will conduct Random inspections to ensure ongoing compliance	10.30.16
A 338	TAC 139.55(b)(6) Clinical Records (b) A licensed abortion facility shall establish and maintain a clinical record for each patient. A licensed abortion facility shall maintain the record to assure that the care and services provided to each patient is completely and accurately documented, and readily and systematically organized to facilitate the compilation and retrieval of information. Information required for the annual abortion report shall be readily	A 338		

Texas Department of State Health Services

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A 338	Continued From page 20 retrievable from the clinical record. (6) A facility shall maintain clinical records in their original state. Each entry shall be accurate, dated with the date of entry, and signed by the individual making the entry. Correction fluid or tape shall not be used in the record. Corrections shall be made by striking through the error with a single line, and shall include the date the correction was made and the initials of the person making the correction. This Requirement is not met as evidenced by: Based on record review and interview, the staff failed to document the date and a legible signature in 11 of 11 (#1-#11) clinical records reviewed. Findings: A review of the clinical records for 11 patients (#1 through #11) revealed the entries had no date and the signature was an illegible initial. There was no way to know if the staff member was a nurse performing the recovery period of the patient and discharging the patient from the facility. An interview with Consultant and Charge Nurse on 08/16/2016 at 3:00 PM confirmed that they did not recognize the illegible initial and that there was no date with the initial.	A 338	Nursing supervisor shall conduct training for all Medical staff on proper documentation, to include legible signature or legible initials with title in clinical Records. All clinical records have date at top of page including recovery page (See attachment #9)	
A 364	TAC 139.57(c)(1)(A)(B)(C)(2) Discharge And Follow-Up Referrals (c) The facility shall develop and implement written policies and procedures for: (1) examination or referral of all patients who	A 364		

Texas Department of State Health Services

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A 364	Continued From page 21 report complications, as identified in the list required by subsection (a)(1) of this section, to the facility after an abortion procedure. The written policy and procedure shall require: (A) the facility to maintain a written system of documentation of patients who report post-abortion complications within 14 days of the procedure date; (B) documentation of the facility's action following a patient's reporting of post-abortion complications to be placed in the patient's record; and (C) the patients' records to be maintained for adults for seven years and for minors five years past the age the patient reaches majority; and (2) periodic review of the record keeping system for post-abortion complications to identify problems and potential problems and to make changes in order to resolve the problems. This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to develop and implement written policies and procedures. The facility failed to maintain a written system of documentation regarding follow-up care for 1 of 1 patients (#1) who reported post-abortion complications. Findings include: Record review of the facility clinical records for Patient #1 revealed that she was a 32 year old female who was seen on 7-26-16 for a medical abortion procedure. Further review revealed that the patient called the facility on 7-31-16, 8-01-16, and 8-03-16 complaining of a fever of 102.8 F, Chills, and passing blood clots which exuded a foul odor. The facility Registered Nurse (RN) advised the patient to go to the Emergency Room	A 364	Nursing Supervisor shall develop policy and procedure for follow up once patient has Reported possible complication with in 14 days of the procedure This will include facility's plan for follow-up with patient to check on status. Documentation will be in patient record and in facility call log. All nursing staff handling patient calls or encounters will be advised / trained on policy. QA committee will review as on going part of monitoring complications	10.30.16

Texas Department of State Health Services

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A 364	Continued From page 22 to seek treatment. The patient record contains no evidence that the facility RN attempted to contact Patient #1 to inquire about her condition and /or if she sought treatment at anytime during the time period of 7-31-16 to the time of the survey (8-16-16). Record review of the facility's policies and procedures on 8/16/16, revealed no evidence that the facility had developed/implemented policies relating to post procedure patient follow-up and monitoring of post-procedure infections. In an Interview conducted on 8-16-16 at 3:10 p.m., the facility Charge nurse confirmed that follow-up calls to Patient #1 had not been conducted, and that facility staff were unsure whether the patient had sought medical treatment or what her current health disposition was at the time of the interview (8-16-16). In an Interview conducted on 8-16-16 at 3:15 p.m., the facility Consultant also confirmed the above findings. The Consultant revealed that the facility does not have a policy/process for patient post procedure follow-up.	A 364	Pt was referred to E.R on 7/31, 8/1 & 8/3 by staff nurse. (See attachment #10) Nursing supervisor will develop policy for follow up on possible post abortion complication calls that will include facility's policy on attempts to contact patients QA committe will review as part of on-going evaluation of complication	10.30.16
A 391	TAC 139.60(a) Other State and Federal Compliance Rqmts (a) A licensed abortion facility shall be in compliance with all state and federal laws pertaining to handling of drugs. This Requirement is not met as evidenced by: Based on observation and interviews, the facility	A 391		

Texas Department of State Health Services

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A 391	Continued From page 23 failed to ensure drugs listed in schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act were kept locked and under proper security. The facility failed to ensure Schedule II- V narcotic medications were kept locked within a secure area where unauthorized personnel and patients were not permitted access. Findings include: Observations conducted on 8/16/16 from 9:30 am to 4:30 pm, in the facility revealed the following: Procedure Room #3: * 24 pre-filled syringes which were unlabeled/undated were being stored in an unlocked cabinet underneath the surgical suction machine. In an interview conducted at the time of discovery, the Charge Nurse revealed that two (2) of the syringes contained Valium, One (1) contained Stadol, One (1) contained Romazicon, and the other Twenty (20) contained Chloroprocaine. Medication Area: * The medication area consisted of an open bay (No Door) which was situated along a common hallway where patients waited for procedures. At the time of observation there were 8 patients and unlicensed staff sitting/waiting in the hallway, within 5 feet of the open medication area. Within the medication area, narcotic medications were kept in cabinets under a single lock, and without	A 391	Nursing supervisor will develop policy for storage of Schedule II-V narcotic medications to be locked and properly secured. QA committee will conduct random inspections to ensure facilitys compliance	10/30/16

Texas Department of State Health Services

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A 391	Continued From page 24 supplemental interior lock boxes. The cabinets contained Two Hundred (200) bottles of Tylenol #3 (with Codeine), containing Ten (10) tablets each (2000 tablets). In addition, the cabinets also contained Stadol, Valium, and Ativan injectable vials. * On the countertop within the medication area (unsecured) was a portable lock box which contained pre-drawn syringes of Valium, Ativan, and Stadol for use in procedure rooms. In an interview at the time of observation, The Charge Nurse confirmed the above findings, stating that she was unaware of the requirement to keep schedule II, III, IV, and V narcotic medications locked within a secure area. When asked by the surveyor if the facility had a policy governing the security of scheduled narcotics, the Charge Nurse stated there was no policy.	A 391	Administrator will obtain additional locks for cabinets providing a double lock-system for storage of narcotic medication Nurse supervisor will develop policy for storage of narcotic medication in Schedule II-V to be locked and properly stored. All nursing staff will be advised of facility policy. QA committee will conduct Random inspections to ensure facility's compliance.	10.30.16