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
	008137	A. BUILDING: _____ B. WING _____	10/03/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMANS HEALTH OF BEAUMONT	440 18TH ST STE A BEAUMONT, TX 77703

(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 on-site unannounced survey was initiated with an entrance conference on 10/2/2013 at 8:00 AM. at the facility located at 440 18th Street, Beaumont, Texas. The entrance conference was held in the Administrator's office with the Administrator in attendance. The purpose of the survey and the survey process were explained. An opportunity was provided for questions and discussion. A survey was conducted per 25 TAC 139.31 to determine the abortion facility's compliance with the requirements at 25 TAC 139 (Abortion Facility Reporting and Licensing Rules) - using the applicable survey report form. An exit conference was held on 10/3/2013 at 11:30 AM. in the Administrator's office with the Administrator and the Associate Director in attendance. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for questions and discussion.	A 000		
A 119	[redacted]	A 119		

SOD - State Form

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

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A 119	Continued From page 1 [redacted]	A 119		
A 121	[redacted]	A 121		

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A 121	Continued From page 2	A 121		
	[redacted]			
A 125	[redacted]	A 125		

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A 125	Continued From page 3 [redacted]	A 125		

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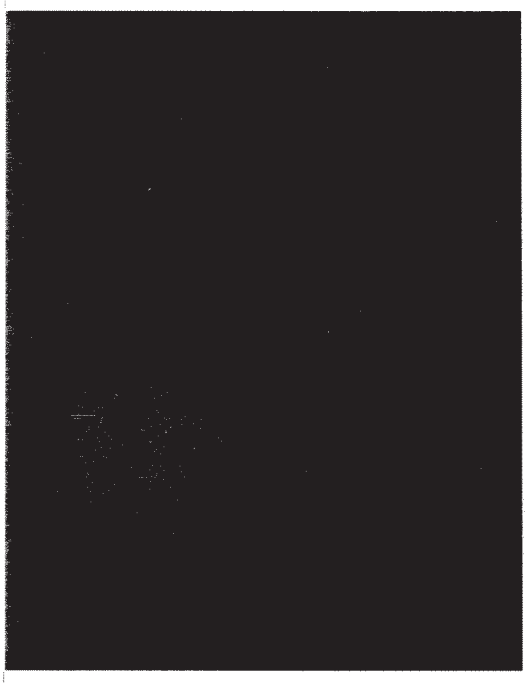
A 281	139.47(b)(13) Facility Administration 	A 281		
A 283	139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and 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 provide a safe environment for patients	A 283		

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A 283	Continued From page 5 and staff. Findings Included: During the tour of the facility on 10/2/2013 at 10:00 AM, observation in the hallway where oxygen tanks were stored and secured with a chain revealed 2 E-cylinders (oxygen tanks) were left outside of the chain. The oxygen tanks were stored in the main hallway of the facility. The unsecured oxygen tank had the likelihood of being knocked over which is a safety hazard for patients and staff. During the tour of the facility on 10/2/2013 at 11:00 AM, observation in the pathology room under the sink revealed a large hole in the cabinet flooring. The hole was approximately 6 inches in diameter and the wood was splintered around the edges. The facility was storing sterilization solutions for cleaning instruments around the hole in the floor. The hole in the flooring had the likelihood to allow rodents to enter the facility and the splintered wood edges could puncture the sterilization solutions. An interview with the administrator on 10/2/2013 at 11:00 AM confirmed the above findings.	A 283		
A 284	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;	A 284		

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A 284	Continued From page 6 This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to provide safe and sanitary equipment in the patients' procedure rooms. Findings Included: During the tour of the facility on 10/2/2013 at 9:30 AM observation of the procedure room #1 and #2, there were numerous rusty spots on the suction machines used on the patient for evacuation of the products of conception. This had the likelihood to cause infection due to the inability to clean the surface area of the machines appropriately. An interview with the administrator on 10/2/2013 at 10:00 AM confirmed in procedure room #1, and #2 that there were numerous rusty spots on the suction machines which were being used on patients for the evacuation of the products of conception.	A 284		
A 406	139.53(7) Medical and Clinical Services (b) Medical abortion. (7) A licensed abortion facility shall provide the patient with written discharge instructions including a direct referral to a physician who will accept the patient for surgical abortion. This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to document in patient #9's clinical record a referral to another facility and follow the facility's own policy. The patient's gestation did not fall within the the parameters of the providing	A 406		

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A 406	Continued From page 7 physician at this facility. A review of the policy titled, "Whole Woman's Health of Beaumont Referral Policy" revealed: "Any patient of Whole Woman's Health who is seeking a service not provided by the clinic will be offered referrals to other facilities, If possible, three referrals will be offered in an objective manner. There will be a list of referrals available for staff to access and give out information as necessary. Reasons for referral include, but are not limited to: *Patient's gestation does not fall within the parameters of the providing physician *Patient's medical history precludes her from safe medical care in this facility *Patient seeks obstetrical care *Patient demonstrates need for further medical attention in an area which Whole Woman's Health does not specialize *Patient requests referral for any reason." A review of patient #9's clinical record revealed no documentation of a referral to another facility. Ultrasound report documentation revealed "15w5d (15 weeks, 5 days)". The only documentation written on the clinical record was "TOO FAR" and on "Surgical Abortion Record" "reason for no abortion: referred to San Antonio" no documentation of referral or discharge instructions given to the patient. The patient's gestation did not fall within the parameters of the providing physician at this facility according to the referral policy. An interview with the Administrator on 10/3/2013 at approximately 9:00 AM confirmed the clinical record did not have documentation that the	A 406		

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A 406	Continued From page 8 patient received a referral or discharge instructions and the facility had not followed their own policy.	A 406		
A 422	[redacted]	A 422		

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A 422	Continued From page 9	A 422		
A 423	[redacted]	A 423		
A 426	[redacted]	A 426		

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A 426	Continued From page 10	A 426		
				
A 455	139.57(c)(1)(B) Discharge and Follow-up (c) The facility shall develop and implement written policies and procedures for: (1) examination or referral of all patients who report complications, as identifiedin the list required by subsection (a)(1) of this section, to the facility after an abortion procedure.The written policy and procedure shall require: (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 This Requirement is not met as evidenced by:	A 455		

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A 455	Continued From page 11 Based on record review and interview, the facility failed to file the post abortion complication call back forms in the patients' clinical record in 18 of 18 (#3, 12, 13, 14, 15, 16, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, and 29) and follow the facility's policy. A review of the policy titled, "Protocol: Post -Operative Problem Triage and Standing Orders" revealed: "Whole Woman's Health will have an after-hours message. The message will state that for further problems, a licensed professional may be contacted through an answering service, and that number will be given. Whole Woman's Health will supply after hours licensed personnel providing this service with: * A cell phone or pager * Documentation forms * Current Whole Woman's protocols and referrals The licensed personnel receiving the pages from patients must return the call in a safe(not while driving) and timely fashion. The licensed personnel will document any attempted and successful patient contacts. This documention will become a part of the patient's permanent medical record." Record review of the form titled, "Post TOP (termination of pregnancy)/Mife (Mifepristone) Call Back" form revealed 18 call back forms present in a folder. The forms contained documentation of the patient's condition with instructions to the patient's complaint from staff members. The patient's clinical record revealed no complaint documentation present in the clinical record.	A 455		

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A 455	Continued From page 12 An interview with the Administrator on 10/2/2013 at approximately 4:30 PM confirmed the policy had not been followed and the "Post TOP/Mife Call Back" forms were not filed in the clinical record.	A 455		
A 457	139.57(c)(2) Discharge and Follow-up (c) The facility shall develop and implement written policies and procedures for: (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 have a policy or procedure for patients being assessed at the facility who have the likelihood for developing health problems that had been discovered during their visit on 2 (#10 and #13) of 29 clinical records reviewed. A review of patient #10 clinical record revealed on the history and physical that the patient had a questionable bladder mass (no date of when physician completed the history and physical). Patient had been sent for a obstetric ultrasound at an offsite facility on 08/06/2013. Patient had abortion procedure on 08/07/2013. Further documentation in the clinical record revealed an entry of a blood pressure of 156/108 and the blood pressure had been circled, "cramping!! menstrual bleeding small amt. of tissue and clots in uterus and echo." This record of documentation revealed no patient name, no signature of a staff member or physician, or date.	A 457		

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A 457	Continued From page 13 The record revealed numerous blanks and a picture from the sonogram machine initialed by the physician dated 08/08/2013. Discharge record revealed no mention of the ultrasound results discussed with the patient. Patient arrived at the facility at 12:10 PM with blood pressure of 144/93, and the last blood pressure taken was 155/111 at 2:00 PM; discharged home at 2:20 PM. A review of patient #13 clinical record revealed the history and physical had not been signed by a physician. This patient's clinical record had documentation that the patient had a 6 X 8 cm left adrenal mass with calcification on the history and physical. The clinical record revealed no documented discharge instructions or follow-up for the patient concerning the adrenal mass. An interview with the Administrator on 10/3/2013 at 10:00 AM confirmed patient #10 and #13 had no documentation that the health issues found during the patient's visit to the facility had been followed up with by a staff member or the physician.	A 457		
A 480	139.59(j)(2)(D) Anesthesia Services (2) In addition to the equipment and supplies required under paragraph (1) of this subsection, facilities which provide moderate sedation/analgesia, deep sedation/analgesia, regional analgesia and/or general anesthesia shall provide the following: (D) electrocardiographic monitoring equipment; This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to have the electrocardiograph monitoring	A 480		

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A 480	Continued From page 14 equipment ready if an emergency situation occurred in the facility. During the tour of the facility on 10/02/2013 at approximately 10:00 AM observation revealed the cardiac defibrillator had no electrocardiograph recording paper in the machine. Also observed, the cables to the defibrillator were not connected. The Administrator was observed trying to replace the recording paper in the defibrillator, but was unable to feed the paper correctly into the machine. In an emergency situation this has the likelihood to cause harm to the patient. An interview with the Administrator on 10/2/2013 at 10:00 AM confirmed the cardiac defibrillator was out of paper and the cardiac cables were disconnected from the machine.	A 480		
A 483	139.60(a) State and Federal Requirements (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, record review and interview, the facility's Quality Assurance Committee failed to have systems in place to evaluate the facility's medication therapy practices and to ensure outdated medication were not available for patient use.	A 483		

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A 483	Continued From page 15 Findings Included: During a tour of the facility observed on 10/2/13 at approximately 10:30 AM with the Administrator, the following medication practices were observed and found expired drugs in the procedure room and in the pathology room. Observed in procedure room in a cabinet drawer was a 50 cc bottle of Lidocaine 1% (labeled with Vasopressin) with an 18 gauge needle stuck in the rubber stopper of the bottle open to air. The Lidocaine bottle was dated 10/1/2013 which was from the day before when procedures had been conducted in the facility. Observed in pathology room in the drawer of the metal file cabinet were pre-filled medication cups with approximately 2-4 pills in each cup. The medication cups were not labeled with patient's name, name of the medication, nor the strength of the medication. Also, observed were medication cups that had turned over and pills had fallen out of the medication cups. Surveyor questioned staff #9 how they would know which cup the medication belongs in. Staff #9 stated, "by the size of the pill." This medication practice had the likelihood to cause an error in the patients receiving a wrong dose of medication being given to the patient and an infection to the patient. Intravenous solutions Lactated Ringers 1000 cc X 5 expired August 2013 were found in the procedure room available for patient use. Magnesium Sulfate vials X 15 expired September 2013 were found in the pathology room available for patient use.	A 483		

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A 483	Continued From page 16 An interview with the Administrator on 10/2/2013 at approximately 11:00 AM confirmed the above findings.	A 483		
A 488	139.60(f) State and Federal Requirements (f) A licensed abortion facility utilizing the services of a licensed vocational nurse(s) shall ensure that its vocational nurse(s) comply with the Nursing Practice Act, Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility. This Requirement is not met as evidenced by: Based on record review and interview, the licensed vocational nurse at the facility failed to legibly write her name and credentials on 12 of 29 records reviewed. A review of 12 clinical records revealed only the initials of the licensed vocational nurse had been documented and it was undetermined what her credentials were supposed to be and the signature was not legible enough to read. Surveyor questioned Administrator as to who was signing and administering the medication. Refer to,"Title 22 Examining Boards, Part 11 Texas Medical Board of Nursing, Chapter 217 Licensure, Peer Assistance and Practice, Rule 217.10." An interview the Administrator on 10/3/2013 at approximately 10:00 AM confirmed the above findings.	A 488		