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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
	140000	A. BUILDING _____ B. WING _____	03/15/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMANS HEALTH OF FORT WORTH, LLC	1717 SOUTH MAIN STREET FORT WORTH, TX 76110

(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 on site. An entrance conference was held with the facility Administrator and the Clinical Manager (Personnel #1 and #2) at 8:00 AM on 03/14/11 to explain the purpose and process, that is, to ascertain compliance with the requirements at 25 TAC 139 - Texas Abortion Facility Reporting and Licensing Rules. Survey findings for the Re-licensure survey was discussed with the facility Administrator (Personnel #1), and by conference call with the Director of Medical Services for the company (Personnel #7), at an exit conference at 4:30 PM on 03/15/11. They were provided the opportunity to respond to the investigation findings and to provide evidence of compliance with regulations surveyed. Survey findings will be sent by e-mail, and a plan of correction for any deficiencies noted should be returned to the Arlington Zone office within 14 calendar days. Recommend Re-licensure of this Abortion Facility. Deficiencies cited.	A 000	[redacted]	
A 228	[redacted]	A 228		

[redacted]

TITLE: Director of Medical Services (X6) DATE: 4/22/11

VGV811

If continuation sheet 1 of 13

PIC acceptable 4/26 BP

§245.023

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A 229	Continued From page 1	A 229		

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A 229	Continued From page 2	A 229		

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A 229	Continued From page 3	A 229		

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A 229	Continued From page 4 [redacted]	A 229		

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A 283	Continued From page 5	A 283		
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 had not ensured a safe environment, equipped to protect the health and safety of their clients, in that, they had: A) expired equipment (curettes), in 1 of 2 operating rooms, and B) expired medications in the Medication Area, where these items had been available for client use. Findings included: During a tour of the facility at 11:40 AM on 03/14/11 with the Clinical Director (Personnel #2), the surveyor observed the following: A) 5 - curettes, expired 07/10, in operating room #2. B) 22 - Gentamicin injectable, 80 mg/2 ml, expired 03/01/11, in the Medication Area. 3 - Ampicillin injectable, 2 gram bottles, expired 02/11, in the Medication Area. In an interview at 8:40 AM on 03/15/11 with the Clinical Director (Personnel #2), she verified that the above equipment was expired, and had been available for client use.	A 283	**A 283-** Staff re-training on proper infection control and disposal of expired or unused medications and medical supplies. Completed by 4/30/11 Effective immediately (3/15/11) all expired medicines and medical supplies were removed from the facility according to OSHA and WWH infection control management policies. Completed 3/15/11 The Administrator of the facility will now monitor and supervise the process for all medicine and medical supply inventory and for purging those that are expired or unused. Effective 3/15/11	

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A 287	Continued From page 6	A 287	A 287 All liquids in the facility will be labeled according to the composition and expiration date. Completed by 4/30/11	
A 287	139.48(1)(E) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; This Requirement is not met as evidenced by: Based on observation and interview, the facility had not ensured a safe environment, in that, they had not labeled an unidentified liquid used in 2 of 2 operating rooms. Findings included: During a tour of the facility at 11:40 AM on 03/14/11 with the Clinical Director (Personnel #2), the surveyor observed an unlabeled purple spray bottle, which contained a dark liquid, in each of the 2 operating rooms. In an interview at 8:40 AM on 03/15/11 with the Clinical Director (Personnel #2), she was asked what the dark liquid was, and she said it was Betadine, used during the surgical procedures. She stated the Betadine bottles were usually labeled, but they had just gotten these new bottles, and she confirmed they had not been labeled as to their contents.	A 287		
A 326	139.49(d)(5)(C)(iii) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.	A 326	A 326- An in-service will be provided to all staff responsible for decontamination and sterilization process to ensure understanding and compliance with OSHA and WWH infection control, decontamination, and sterilization process, including open position of hinged instruments. Completed by 4/30/11 As part of Whole Woman's Health Internal Q/A Process, the Administrator will supervise this process to ensure best practice. On-Going Supervision	

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A 326	Continued From page 7 (5) Equipment and sterilization procedures. (C) Preparation for sterilization. (iii) All articles to be sterilized shall be arranged so all surfaces shall be directly exposed to the sterilizing agent for the prescribed time and temperature. This Requirement is not met as evidenced by: Based on observation, interview, and record review, the facility did not correctly arrange all equipment to be sterilized, in that, 2 of 3 areas where sterile supplies were stored contained packages of tenaculums that had been sterilized in the "closed" position. Findings included: On a tour of the facility at 10:40 AM on 03/14/11 with the Clinical Director (Personnel #2), the surveyor observed the following packaged sterilized instruments had not been arranged where the point of the greatest bio-burden was directly exposed to the sterilizing agent: -The Pathology Room had 1 sterile packaged tenaculum that had been sterilized with the tips "closed." -Surgery Room #2 had 4 sterile packaged tenaculums that had been sterilized with the tips "closed." A review of the facility "Procedure for Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies,: policy, last reviewed 10/09, required that "all instruments to be sterilized will be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature."	A 326		

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A 326	Continued From page 8 In an interview at 11:00 AM on 03/14/11 with the Clinical Director (Personnel #2), she verified the above sterilized items had been packaged with the tips of the instruments in a "closed" position that did not allow for the point of the greatest bio-burden to be exposed to the sterilizing agent.	A 326		
A 446	139.56(c) Emergency Services (c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities. This Requirement is not met as evidenced by: Based on interview and record review, the facility had not ensured all staff providing direct patient care were currently certified in basic life support, and as required in their job descriptions for 3 of 3 clinical staff (Personnel #2, # 3 and #4). Findings included: Review of personnel records for three clinical staff personnel who were providing direct patient care during the survey on 03/14/11, revealed the following: Personnel #2: Her job description as the Clinical Director required she have a cardiopulmonary resuscitation (CPR) certification for providing basic life support. She did not have a current CPR, as it expired on 02/06/11. Personnel #3: Her job description as a Patient	A 446	A 446 A CPR class has been scheduled on-site to recertify staff in BCLS who are providing direct patient care. Completed 4/30/11	

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A 446	Continued From page 9 Advocate required she have a cardiopulmonary resuscitation (CPR) certification for providing basic life support. She did not have a current CPR, as it expired on 10/05/10. Personnel #4: Her job description as a Patient Advocate required she have a cardiopulmonary resuscitation (CPR) certification for providing basic life support. She did not have a current CPR, as it expired on 02/10. In individual interviews at 1:30 PM on 03/14/11 with Personnel #2, #3 and #4, they each verified they were required to have a current CPR, and their CPR certifications for providing basic life support had expired.	A 446		
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, interviews, and record review, the facility: A) was not in compliance with all state and federal laws pertaining to handling of drugs, and B) had not followed their drug security policy, in that, drugs had not been secured in 2 of 2 operating rooms, the Medication Area, and in the Counseling hallway file cabinet. Findings included: During a tour of the facility at 11:40 AM on 03/14/11 with the Clinical Director (Personnel #2),	A 483	A 483 An In-service will be provided to all staff responsible for handling medications to re-train on proper storage of controlled and non-controlled medications. A lock will be installed in the designated area to contain the locked box containing all controlled medications so they are properly stored and secured, in a double locked area. All non-controlled medications will be kept in a secure locked area to ensure safety. All to be Completed by 4/30/11	

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A 483	Continued From page 10 the surveyor observed the following unsecured drugs: Operating Room #1: 2 - Atropine, injectable, 0.4 milligrams/milliliter (mg/ml) bottles, in an unlocked drawer. Operating Room #2: 2 - Atropine, injectable, 0.4 mg/ml bottles, in an unlocked drawer. Medication Area: The Medication Area consisted of an open, side hallway, located off the main clinical hallway used by clients to get to the Recovery Room, and had no door for security. This open hallway was where the facility's medications were kept in unlocked cabinets, in an unlocked refrigerator, and also where their safe (for controlled medications) sat on the counter top. At the time this area was toured, the safe was unlocked. The following was observed: Medication in unlocked safe: 15 - Atropine injectable, 0.4 mg/ml. 8 - Atropine injectable, 0.1 mg/ml. Medication sitting out on the counter top. 4 - Lidocaine 1% injectable, 10 mg/ml, unopened. 8 - Lidocaine 1% injectable, 10 mg/ml, opened. Medication in unlocked cabinets: 43 - Gentamicin injectable, 80 mg/2 ml. 19 - Vasopressin injectable, 20 units/ml. 13 - Ampicillin injectable, 2 gram bottles. 74 - Pitocin injectable, 10 units/ml. Medication in unlocked refrigerator: Rhogam and Micro Rhogam Cytotec	A 483		

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A 483	Continued From page 11 Depo-Provera Medication in unlocked file cabinet, in the Counseling hallway: 33 - Cytotec (misoprostol), 200 microgram tablets, used for pregnancy termination. In an interview at 12:00 PM on 03/14/11 with the Clinical Director (:Personnel #2), she was asked if the medication cabinets were usually locked, and she said "no." When asked why the safe, used for controlled drugs, was not locked, she said she had "unlocked it, to make it easier for the surveyor to check." She verified that clients use the main hallway, passing by the open Medication Area, to get to the Recovery Room. In an interview at 12:30 PM with the Licensed Vocational Nurse (LVN), (Personnel #11), she was asked why Cytotec pills would be kept in an unlocked file cabinet, away from other medications used in the facility, and she said "she didn't know." She verified that an opened bottle of 33 Cytotec tablets were in an unlocked file cabinet in the Counseling hallway. The facility's "Procedure for Handling Controlled Medications," policy, dated 12/07, noted that "controlled medications must be secured behind two locks, i.e. in a safe, in a lockable room." The state rules & regulations found at 25 Texas Administrative Code, 133.41(q)(4)(c), requires that "drugs...shall be properly stored to ensure...security." The federal rules & regulations found at 482 Code of Federal Regulations, requires that: -At 482.25(b), "in order to provide patient safety, drugs...must be controlled...in accordance with	A 483		

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A 483	Continued From page 12 applicable standards of practice, consistent with Federal and State law." -At 482.25(b)(2)(i), all drugs must be kept in a secure area, and locked when appropriate."	A 483		