| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
|---|---|---|---|
| | 140013 | A. BUILDING: _____ B. WING _____ | 07/24/2017 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| WHOLE WOMAN'S HEALTH ALLIANCE | 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753 |

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| A 000 | TAC 139 Initial Comments<br><br>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.<br>An entrance conference was held with the Clinic Nurse Manager the morning of 7-24-17. The purpose and process of the initial licensure survey were discussed, and an opportunity given for questions.<br><br>Initial licensure is recommended, with an approved plan of correction.<br><br>An exit conference was held with the Clinic Nurse Manager and the Director of Clinical Services on the afternoon of 7-24-17. Preliminary findings of the survey were discussed, and an opportunity given for questions. | A 000 | Reviewed 8-7-17 by Wanda Wilson, RN | |
| A 126 | TAC 139.41(a) Policy Development and Review<br><br>(a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following: | A 126 | | |

[redacted] ATIVE'S SIGNATURE Director of Clinical Services TITLE 08/04/2017 (X6) DATE

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| A 126 | Continued From page 1<br><br>This Requirement is not met as evidenced by:<br>Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment.<br><br>Findings were:<br><br>During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 ml of Fentanyl was present in boxed vials. 2 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringes, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl, for a total of 153 ml of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcotic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #6 and staff #9). In an interview with staff members #6 & #7, neither member was able to explain the 1 ml Fentanyl discrepancy and both staff stated that no patients had been seen since 7-21-17.<br><br>According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule II drug is described as follows: "Schedule II/IIN Controlled Substances (2/2N)<br><br>Substances in this schedule have a high potential for abuse which may lead to severe psychological | A 126 | A 126<br><br>The Clinic Manager is responsible for ensuring compliance with all policies governing the facility operations.<br><br>Whole Woman's Health Alliance (WWHA) complies with the policy and review requirement for abortion facilities by developing and following The WWHA Medication Therapy Practices. The error identified by the surveyors was related to a clerical miscount, and not to any missing doses. The Clinic Manager conducted and audit of the controlled substances during the survey, and found the miscount error which was immediately corrected.<br><br>A staff in-service was facilitated on 7/24/17 in order to train staff on how to properly count, document the medications, and to reinforce understanding of the existing Medication Therapy Practices policy.<br><br>In our order to monitor compliance, in addition to the daily open and close counts, a monthly audit of the control substances log will be conducted by the Clinical Coordinator and reviewed by the Clinic Manager. | 07/24/17 |

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| A 126 | Continued From page 2<br>or physical dependence.<br><br>Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.<br><br>Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).<br><br>Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital."<br><br>Facility policy titled "Medication Therapy Practices" stated, in part:<br>"Controlled Medications Closing Count"<br>1. Each day that Controlled Medications are administered, at the end of the day, two staff will open the safe and count each drug on the Controlled Medication log.<br>...<br>8. Any discrepancies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager. Discrepancies that cannot be resolved should generate a Narcotics Deviation Report. Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and included in the Quarterly Review."<br><br>The above was confirmed in an interview with staff #6 and staff #7 on the afternoon of 7-24-17. | A 126 | | |

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| A 257 | Continued From page 3 | A 257 | | |
| A 257 | TAC 139.49(d)(5)(L)((ii)(I - V) Infection Control Standards<br><br>(L) Performance records.<br>(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include:<br>(I) the sterilizer identification;<br>(II) sterilization date and time;<br>(III) load number;<br>(IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts);<br>(V) identification of operator(s);<br><br>This Requirement is not met as evidenced by:<br>Based on a review of performance records and interview, the facility failed to ensure that each sterilizer was monitored during operation for pressure, temperature, and time at desired temperature and pressure, as evidenced by the fact that a record was not maintained that included: duration and temperature of exposure phase (if not provided on sterilizer recording charts).<br><br>Finding included:<br><br>Review of the autoclave logs for May, June, and July 2017 revealed that pressure, temperature, and duration of exposure at desired temperature and pressure of the sterilized logs was not documented.<br><br>In an interview on 07/24/17, staff member #7 stated that the new autoclave forms have an area to document the pressure and temperature, | A 257 | A 257<br><br>The Clinic Manager is responsible for monitoring proper documentation of infection control standards.<br><br>Whole Woman's Health Alliance has accurate confirmation that all instruments have been properly sterilized.<br>In addition to the autoclave load logs the facility uses special sterilization pouches, sterilization strips, and sterilization tape that automatically confirms instruments are properly sterile without requiring staff documentation.<br><br>The autoclave load log in question has been updated to include the pressure, temperature, and time of sterilization process.<br><br>A staff in-service will be facilitated on 08/09/17 in order to train staff on the updated log and how to properly document.<br><br>In order to monitor compliance, the Clinical Coordinator will conduct a monthly audit of the logs, any findings needing attention will be presented to the clinic manager to address proper documentation is in place. | 08/09/2017 |

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| A 257 | Continued From page 4<br>however the facility was utilizing old logs that did not contain a prompt to document this information. The new forms also did not have an area to document duration of the exposure phase.<br><br>With no documentation of these elements it is unknown if these loads and instruments were effectively sterilized.<br><br>Facility policy titled "Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" states, in part:<br>"Performance Records<br>Performance records for all sterilizers will be maintained for each cycle. And will be retained for two years.(sic) These records will be available for review within two hours during the specified two-year period.<br><br>All sterilizers will be monitored during operation for pressure, temperature, and time at desired temperature and pressure. The performance record will include:<br>-Sterilizer identification number<br>-Sterilization date<br>-Sterilization time<br>-Load number<br>-Pack ID#'<br>-Duration and temperature of exposed phase<br>-Identification of operator<br>-Results of biological tests and dates performed<br>-Time/temperature recording charts from each sterilizer"<br><br>The above findings we confirmed on 07/24/17 in an interview with staff member #7. | A 257 | | |

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| A 315 | Continued From page 5 | A 315 | | |
| A 315 | House Bill 2 Medical and Clinical Services<br><br>A physician must provider the pregnant woman with: a) a telephone number by which the pregnant woman may reach the physician, 24 hours a day to request assistance for any complications that arise from the abortion or ask health-related questions regarding the abortion; and b) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.<br><br>This Requirement is not met as evidenced by:<br>Based on a review of clinical records and an interview with staff, the physician failed to provide the pregnant women with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.<br><br>Findings were:<br><br>During a review of 21 clinical records, 10 of the 21 records (patients #2, #3, #4, #5, #6, #12, #13, #14, #15 and #16) contained no documentation that the patient had been furnished with the name and/or telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.<br><br>-Patients #2, #3, #4, #5 and #6 had been provided with a hospital name but no telephone number for the hospital.<br><br>-Patients #12, #13, #14, #15 and #16 had been | A 315 | A 315<br><br>The Clinic Manager is responsible for ensuring compliance with all policies regarding medical and clinical services.<br><br>Whole Woman's Health Alliance complies with the requirements set forth in House Bill 2 by providing patients with the written name and phone number of the hospital nearest to them at the time of their discharge from our care.<br><br>A staff in service will be facilitated on 08/09/17 to re train staff to document this information on the discharge section of the patient's abortion record.<br><br>In order to monitor compliance, patient charts will be audited at the end of every clinic day, as well as a random monthly chart audit conducted by clinic staff under the supervision of the Clinic Manager. | 08/09/17 |

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| A 315 | Continued From page 6<br>provided with neither a hospital name nor a telephone number for the hospital.<br><br>The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17. | A 315 | | |
| A 327 | House Bill 2 Medical and Clinical Services<br><br>Physicians must ensure that abortion-inducing drugs are used according to FDA regulations that require the women to visit the physician in person for each of the two doses of the abortion pill, as well as for a follow-up appointment within 14 days. The physician must provide the woman with a copy of the final printed label of the abortion-inducing drug.<br><br>This Requirement is not met as evidenced by:<br>Based on a review of clinical records and an interview with staff, the physician failed to ensure that the patient was scheduled for a follow-up appointment within 14 days.<br><br>Findings were:<br><br>Based on the review of 21 clinical records, 1 of 21 (patient #1) was not scheduled to return to the clinic for a follow-up visit within the required 14 | A 327 | | |

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| A 327 | Continued From page 7<br><br>days (appointment was scheduled for 21 days after).<br><br>The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17. | A 327 | A327<br><br>The Clinic Manager is responsible for ensuring compliance with all medical and clinical services requirements.<br><br>Whole Woman's Health Alliance had taken a proactive approach to schedule follow up appointments by working with the patient's availability to ensure they could return to the clinic for their follow up. Effective immediately, we will schedule follow up appointments for patients receiving the medical abortion pill to be 14 days without exception.<br><br>In order to monitor compliance with this requirement the Administrative Coordinator will supervise the patient follow up schedule on a weekly basis.<br><br>A staff in-service will be facilitated on 08/09/17 in order to ensure staff understanding of this requirement. | 08/09/17 |