

Texas Health and Human Services Commission

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140014 | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 01/15/2019 |
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| NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD CENTER FOR CHOICE | STREET ADDRESS, CITY, STATE, ZIP CODE 12614 SOUTHWEST FREEWAY, SUITE B STAFFORD, TX 77477 |
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| (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 |
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| 6 000 | <p>TAC 139.1 Initial Comments</p> <p>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.</p> <p>(a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Health and Human Services Commission with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171.</p> <p>(b) Scope and applicability.</p> <p>(1) Licensing requirements.</p> <p>(A) A person may not establish or operate an abortion facility in Texas without a license issued under this chapter unless the person is exempt from licensing requirements.</p> <p>(B) The following need not be licensed under this chapter:</p> <p>(i) a hospital licensed under Health and Safety Code, Chapter 241;</p> <p>(ii) an ambulatory surgical center licensed</p> | 6 000 | | |

SOD - State Form
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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| 6 000 | <p>Continued From page 1</p> <p>under Health and Safety Code, Chapter 243; or</p> <p>(iii) the office of a physician licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas, unless the office is used for the purpose of performing more than 50 abortions in any 12-month period.</p> <p>(2) Reporting requirements. All licensed abortion facilities and facilities and persons exempt from licensing shall comply with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed). An entrance conference was held with the facility Administrator 1-14-19. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.</p> <p>Continued licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the facility Administrator the afternoon of 1-15-19. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p> | 6 000 | | |
| 6 007 | <p>[REDACTED]</p> <p>[REDACTED]</p> | 6 007 | | |

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| 6 033 | Continued From page 5 | 6 033 | | |
| 6 033 | <p>TAC 139.48 Physical and Environmental Requirements</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows.</p> <p>(1) A facility shall:</p> <p>(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;</p> <p>(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;</p> <p>(C) have a separate recovery room if moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia are administered at the facility;</p> <p>(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;</p> <p>(E) store hazardous cleaning solutions and compounds in a secure manner and label substances;</p> <p>(F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings.</p> | 6 033 | | |

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| 6 033 | <p>Continued From page 6</p> <p>If other food is provided by the facility, it shall be subject to the requirements of Chapter 228 of this title (relating to Retail Food);</p> <p>(G) provide clean hand washing facilities for patients and staff including running water, and soap;</p> <p>(H) have two functioning sinks and a functioning toilet; and</p> <p>(I) have equipment available to sterilize instruments, equipment, and supplies in accordance with §139.49(d) of this title (relating to Infection Control Standards) before use in the facility.</p> <p>(2) The equipment for vacuum aspiration shall be electrically safe and designed to prevent reverse pump action in facilities that provide vacuum aspiration.</p> <p>(3) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction shall minimize disruptions of existing functions. Access, exit ways, and fire protection shall be maintained so that the safety of the occupants shall not be jeopardized during construction.</p> <p>This Requirement is not met as evidenced by: Based on a tour of the facility, the facility failed to store hazardous cleaning solutions and compounds in a secure manner.</p> <p>Findings were:</p> <p>During a tour of the facility on 1-14-19, exam</p> | 6 033 | | |

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| 6 033 | Continued From page 7 rooms #4 and #6 contained unsecured cleaning solutions and compounds to include Lysol spray, Clorox sanitizing wipes, bleach wipes, Sani-cloths and Virex spray. The above was confirmed in an interview with the Clinic Administrator on the afternoon of 1-15-19. | 6 033 | | |
| 6 041 | TAC 139.56 Emergency Services (a) A licensed abortion facility shall have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The facility shall ensure that the physicians who practice at the facility: (1) have active admitting privileges at a hospital that provides obstetrical or gynecological health care services and is located not further than 30 miles from the abortion facility; (2) provide the pregnant woman with: (A) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of 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. | 6 041 | | |

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| 6 041 | <p>Continued From page 8</p> <p>(b) The facility shall have the necessary equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services).</p> <p>(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.</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the facility failed to ensure that all personnel providing direct patient care were 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.</p> <p>Findings were:</p> <p>A review of personnel records for 6 clinic staff was conducted. Of the 6 staff, 5 of the staff (staff #1, #2, #3, #5 & #6) provided direct patient care. Of these 5 personnel records, 2 of the 5 (staff #3 & #5) contained no documentation of current CPR/BLS certification. In an interview with staff #6, staff #6 confirmed that no documentation of current CPR/BLS could be located.</p> <p>The above was confirmed in an interview with the Clinic Administrator on the afternoon of 1-15-19.</p> | 6 041 | | |

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| 6 042 | Continued From page 9 | 6 042 | | |
| 6 042 | <p>TAC 139.57 Discharge and Follow-up Referrals</p> <p>(a) A licensed abortion facility shall develop and implement written discharge instructions which shall include:</p> <p>(1) a list of complications (developed by the facility in conjunction with a physician who practices in the facility) that warrant the patient contacting the facility, which shall include, but not be limited to:</p> <p>(A) pain;</p> <p>(B) fever; and</p> <p>(C) bleeding;</p> <p>(2) a statement of the facility's plan to respond to the patient in the event the patient experiences any of the complications listed in the discharge instructions to include:</p> <p>(A) a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion;</p> <p>(B) the name and telephone number of the nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated;</p> | 6 042 | | |

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| 6 042 | <p>Continued From page 10</p> <p>(C) assurance that the responding individual shall be a physician, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse; and</p> <p>(D) information that the patient may also contact the emergency medical service or present for care at the emergency room of a hospital in addition to contacting the facility; and</p> <p>(3) information concerning the need for a post-abortion examination.</p> <p>(b) A facility shall provide a patient with a copy of the written discharge instructions described in subsection (a) of this section.</p> <p>(c) The facility shall develop and implement written policies and procedures for:</p> <p>(1) examination or referral of all patients who 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:</p> <p>(A) the facility to maintain a written system of documentation of patients who report post-abortion complications within 14 days of the procedure date;</p> <p>(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</p> <p>(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</p> | 6 042 | | |

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| 6 042 | <p>Continued From page 11</p> <p>(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.</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the abortion facility failed to develop and implement written discharge instructions which shall include:</p> <p>(1) a list of complications (developed by the facility in conjunction with a physician who practices in the facility) that warrant the patient contacting the facility, which shall include, but not be limited to:</p> <p>(A) pain;</p> <p>(B) fever; and</p> <p>(C) bleeding;</p> <p>...</p> <p>(A) a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion;</p> <p>(B) a telephone number by which the patient may reach the physician, or other health care</p> | 6 042 | | |

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| 6 042 | <p>Continued From page 12</p> <p>personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion;</p> <p>Findings were:</p> <p>A total of 9 clinical records were reviewed. Of the 9 records reviewed, none contained documentation that the patient had been provided with the following:</p> <ul style="list-style-type: none"> * a list of complications (developed by the facility in conjunction with a physician who practices in the facility) that warrant the patient contacting the facility, which shall include, but not be limited to pain, fever and bleeding * a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion * a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed or induced with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from | 6 042 | | |

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| 6 042 | <p>Continued From page 13</p> <p>the performance or induction of the abortion or ask health-related questions regarding the abortion</p> <p>In an interview with staff #6, staff #6 stated that all patients were provided with the list of complications as well as a telephone number, but that no documentation of such was kept for the patient's file. Staff #6 also stated that their Informaton Technology department had provided a function whereby the staff member could enter the patient's home zip code and that a list of the names and addresses of the 3 hospitals nearest the patient's home would be generated. Staff #6 confirmed that the name and telephone number of the hospital specifically nearest the patient's home was not provided.</p> <p>The above was confirmed in an interview with the Clinic Administrator on the afternoon of 1-15-19.</p> | 6 042 | | |
| 6 045 | <p>TAC 139.60 Other State and Federal Compliance Requiremen</p> <p>(a) A licensed abortion facility shall be in compliance with all state and federal laws pertaining to handling of drugs.</p> <p>(b) A licensed abortion facility that provides laboratory services shall meet the Clinical Laboratory Improvement Amendments of 1988, 42 United States Code, §263a, Certification of Laboratories (CLIA 1988). CLIA 1988 applies to all facilities with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.</p> <p>(c) A licensed abortion facility shall ensure that its</p> | 6 045 | | |

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| 6 045 | <p>Continued From page 14</p> <p>physicians comply with the Medical Practice Act, Occupations Code, Chapters 151 - 160 and 162 - 165, while functioning in his or her capacity at or for the facility.</p> <p>(d) A licensed abortion facility utilizing the services of a physician assistant(s) shall ensure that its physician assistants comply with the Physician Assistant Licensing Act, Occupations Code, Chapter 204, while functioning in his or her capacity at or for the facility.</p> <p>(e) A licensed abortion facility utilizing the services of a registered nurse shall ensure that its registered nurses comply with the Nursing Practice Act, Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility.</p> <p>(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.</p> <p>(g) A licensed abortion facility that provides pharmacy services shall obtain a license as a pharmacy if required by the Texas Pharmacy Act, Occupations Code, Chapters 551 - 569.</p> <p>(h) A licensed abortion facility shall comply with the following federal Occupational Safety and Health Administration requirements:</p> <p>(1) 29 Code of Federal Regulations, Subpart E, §1910.38, concerning emergency action plan and §1910.39, concerning fire prevention plans;</p> | 6 045 | | |

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| 6 045 | <p>Continued From page 15</p> <p>(2) 29 Code of Federal Regulations, Subpart I, §1910.132, concerning general requirements for personal protective equipment;</p> <p>(3) 29 Code of Federal Regulations, Subpart I, §1910.133, concerning eye and face protection;</p> <p>(4) 29 Code of Federal Regulations, Subpart I, §1910.138, concerning hand protection;</p> <p>(5) 29 Code of Federal Regulations, Subpart K, §1910.151, concerning medical services and first aid;</p> <p>(6) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers;</p> <p>(7) 29 Code of Federal Regulations, Subpart Z, §1910.1030, concerning bloodborne pathogens; and</p> <p>(8) 29 Code of Federal Regulations, Subpart Z, §1910.1200, Appendices A - E, concerning hazard communication (hazardous use of chemicals).</p> <p>(i) A licensed abortion facility shall not use adulterated or misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431.111. Misbranded drugs or devices are described in Health and Safety Code, §431.112.</p> <p>(j) A licensed abortion facility shall not commit a false, misleading, or deceptive act or practice as that term is defined in the Deceptive Trade Practices-Consumer Protection Act, Business</p> | 6 045 | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140014 | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 01/15/2019 |
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| NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD CENTER FOR CHOIC | STREET ADDRESS, CITY, STATE, ZIP CODE 12614 SOUTHWEST FREEWAY, SUITE B STAFFORD, TX 77477 |
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| 6 045 | <p>Continued From page 16 and Commerce Code, §17.46.</p> <p>(k) A licensed abortion facility shall comply with the requirements of the Family Code, §33.002, relating to a Consent Form.</p> <p>(l) A licensed abortion facility shall comply with the requirements of Health and Safety Code, Chapter 171, the Woman's Right to Know Act.</p> <p>(m) A licensed abortion facility shall comply with the requirements of Occupations Code, Chapter 102, Solicitation of Patients.</p> <p>This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the facility failed to comply with the requirements of Health and Safety Code, Chapter 171, the Woman's Right to Know Act.</p> <p>Texas Health & Safety Code Section 171.063 states: "Sec. 171.063. DISTRIBUTION OF ABORTION-INDUCING DRUG. (a) A person may not knowingly give, sell, dispense, administer, provide, or prescribe an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless:</p> <p>(1) the person who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug is a physician; and</p> <p>(2) except as otherwise provided by Subsection (b), the provision, prescription, or administration of the abortion-inducing drug satisfies the</p> | 6 045 | | |

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| 6 045 | <p>Continued From page 17</p> <p>protocol tested and authorized by the United States Food and Drug Administration as outlined in the final printed label of the abortion-inducing drug.</p> <p>(b) A person may provide, prescribe, or administer the abortion-inducing drug in the dosage amount prescribed by the clinical management guidelines defined by the American Congress of Obstetricians and Gynecologists Practice Bulletin as those guidelines existed on January 1, 2013.</p> <p>(c) Before the physician gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug, the physician must examine the pregnant woman and document, in the woman's medical record, the gestational age and intrauterine location of the pregnancy.</p> <p>(d) The physician who gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug shall provide the pregnant woman with:</p> <p>(1) a copy of the final printed label of that abortion-inducing drug; and</p> <p>(2) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the administration or use of the drug or ask health-related questions regarding the administration or use of the drug.</p> <p>(e) The physician who gives, sells, dispenses,</p> | 6 045 | | |

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| 6 045 | <p>Continued From page 18</p> <p>administers, provides, or prescribes the abortion-inducing drug, or the physician's agent, must schedule a follow-up visit for the woman to occur not more than 14 days after the administration or use of the drug. At the follow-up visit, the physician must:</p> <p>(1) confirm that the pregnancy is completely terminated; and</p> <p>(2) assess the degree of bleeding.</p> <p>(f) The physician who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug, or the physician's agent, shall make a reasonable effort to ensure that the woman returns for the scheduled follow-up visit under Subsection (e). The physician or the physician's agent shall document a brief description of any effort made to comply with this subsection, including the date, time, and name of the person making the effort, in the woman's medical record.</p> <p>(g) If a physician gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion as authorized by this section and the physician knows that the woman experiences a serious adverse event, as defined by the MedWatch Reporting System, during or after the administration or use of the drug, the physician shall report the event to the United States Food and Drug Administration through the MedWatch Reporting System not later than the third day after the date the physician learns that the event occurred."</p> <p>Findings were:</p> | 6 045 | | |

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| 6 045 | <p>Continued From page 19</p> <p>The clinical records for 9 patients that had received abortion-inducing drugs were reviewed. None of the 9 records contained documentation of a follow-up appointment made within 14 days of administration of the medication.</p> <p>In an interview with staff #6, staff #6 confirmed that the clinical record contained no documentation of the patient's follow-up appointment.</p> <p>The above was confirmed in an interview with the Clinic Administrator on the afternoon of 1-15-19.</p> | 6 045 | | |