

RECEIVED OCT 27 2016

PRINTED: 10/26/2016
FORM APPROVED

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 880072	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 09/13/2016
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NAME OF PROVIDER OR SUPPLIER WOMEN'S CENTER HOUSTON	STREET ADDRESS, CITY, STATE, ZIP CODE 8200 WEDNESBURY LANE, SUITE 230 HOUSTON, TX 77074
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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 entrance conference was held with the facility office manager on morning of 09/12/16. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions. Continued licensure is recommended, with an approved plan of correction. An exit conference was held with the facility Administrator and other administrative staff on the afternoon of 09/13/16. Preliminary findings of the survey were discussed, and an opportunity given for questions.	A 000	REVIEWED OCT 28 2016 BY: Wanda Wilson, RW	
A 036	[REDACTED]	A 036		

SOD - State Form
LABORATORY DIRECTOR'S OR PROV

SIGNATURE

TITLE

(X6) DATE

STATE FORM

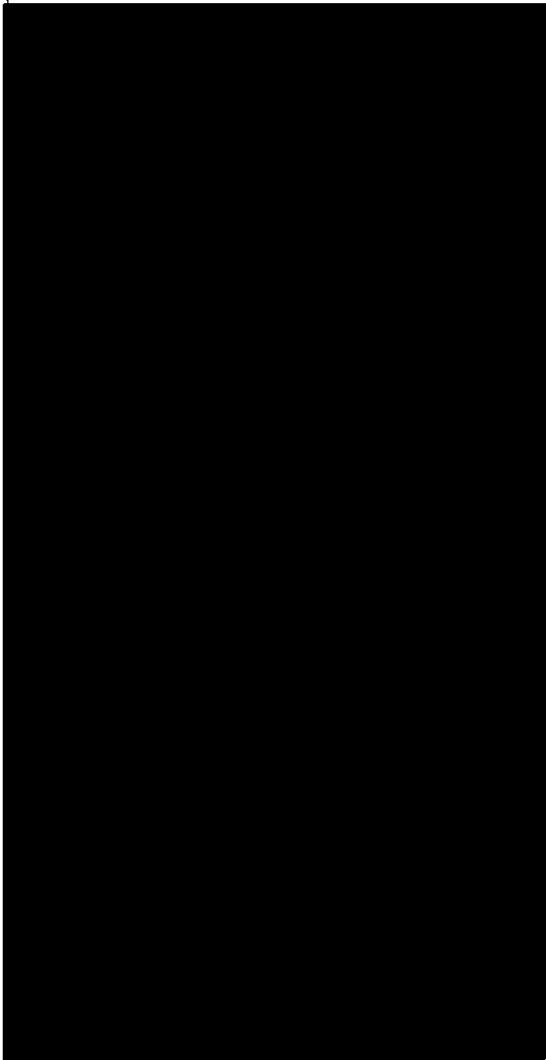
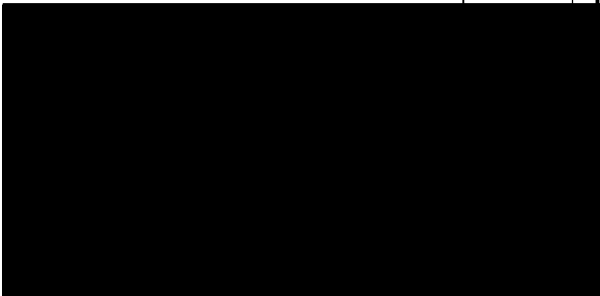
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10/27/16

If continuation sheet 1 of 24

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A 036	Continued From page 1 	A 036		
A 037	TAC 139.8(d)((5)(6)(7) Quality Assurance	A 037		

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A 037	Continued From page 2 (d) Minimum responsibilities. The QA committee shall: (5) address medication therapy practices; (6) address the integrity of surgical instruments, medical equipment, and patient supplies; and (7) address services performed in the facility as they relate to appropriateness of diagnosis and treatment. This Requirement is not met as evidenced by: Based on a review of documentation and interviews, the facility failed to ensure the quality assurance committee addressed medication therapy practices; the integrity of surgical instruments, medical equipment, and patient supplies; and services performed in the facility as they relate to appropriateness of diagnosis and treatment. Findings included: Review of the Quality Assurance Meeting minutes for the calendar year 2016 (on 03/29/16 and 06/30/16) revealed: * The facility failed to address medication practices. * The facility failed to evaluate the the integrity of surgical instruments, medical equipment, and patient supplies. * The facility also failed to review the appropriateness of diagnosis and treatment of patients. In an interview on 09/03/16 staff member #1 confirmed the quality assurance meeting minutes did not include review or addressing the elements listed above.	A 037	The office administrator will provide a daily log sheet for all medications that are being distributed and will be recorded and monitored by the Medical Director. All medications are stored in a metal cabinet with a lock at all times. Only accessible to Medical Director. The Medical Director will provide a review form for the appropriateness of diagnosis and treatment of patients.	12-27-16 12-27-16

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A 038 A 038	Continued From page 3 TAC 139.8(e)(1) Quality Assurance (e) Patient care and service issues. The QA committee shall identify and address patient care services and information issues and implement corrective action plans as necessary. (1) Identifying issues that necessitate corrective action. The QA committee shall be responsible for identifying issues that necessitate corrective action by the committee, such as issues which negatively affect care or services provided to patients. This Requirement is not met as evidenced by: Based on a review of documentation and interviews, the facility failed to ensure the quality assurance committee addressed patient care and service issues. Findings included: Review of the Quality Assurance Meeting minutes for the calendar year 2016 (on 03/29/16 and 06/30/16) revealed: * The facility failed to address any identified patient care and/or service issues. On 09/13/16 staff member #1 confirmed that the above elements were not included in the quality assurance meeting minutes.	A 038 A 038	The office administrator will provide a Quality Assurance committee form for addressed patient care and service issue that will be monitored by Medical Director on a monthly basis.	12-27-16
A 133	TAC 139.41(a)(7)(8)(A)(B) Policy Development and Review (7) policies for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261; and	A 133		

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A 133	<p>Continued From page 4</p> <p>(8) policies to ensure all women who present to obtain an abortion provide identification that includes the woman's date of birth.</p> <p>(A) If the woman does not have identification stating her date of birth, she shall be required to execute an affidavit on a form published by the department indicating that she does not have appropriate identification and indicating her date of birth on the affidavit.</p> <p>Attached Graphic </fids/200902286-1.html></p> <p>Figure: 25 TAC §139.41(a)(8)(A) Affidavit I, _____, swear or affirm that my date of birth is _____, and that I do not have appropriate identification that states my date of birth. Signature: _____ Printed name: _____ Witness: _____</p> <p>_____ Printed name of witness: _____</p> <p>(B) The facility shall keep a copy of the identification presented or the affidavit in its files.</p> <p>This Requirement is not met as evidenced by: The facility failed to ensure there were policies for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261 and that such suspected abuse was screened for and reported.</p>	A 133	The office administrator will provide an affidavit for woman who do not have the proper identification and shall keep a copy of identification presented or the affidavit in its files.	12-27-16

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A 133	Continued From page 5 Findings included: DSHS Child Abuse Screening, Documenting, and Reporting Policy For Contractors Providers Revised effective January 1, 2009 found at http://dshs.texas.gov/childabuse/reporting/gsc_pol.shtm stated in part, "Reporting Suspected Sexual Abuse I. Each contractor/provider shall ensure that its employees, volunteers, or other staff reports a minor under 14 years of age who is pregnant or has a confirmed STD acquired in a manner other than through perinatal transmission or transfusion. A sexually transmitted disease is any disease that is transmitted by any sexual activity as described in §§21.01, 21.11, and 22.011 of the Penal Code, whether reportable or not. II. The Texas Family Code, Chapter 261, requires reporting of various types of sexual abuse. Instances of reportable abuse include but are not limited to, the actions described in: Penal Code, §21.11(a) relating to indecency with a child; Penal Code, §21.01(2) defining "sexual contact " ; Penal Code, §43.01(1) or (3) - (5); or Penal Code, §22.011(a)(2) relating to sexual assault of a child; or Penal Code, §22.021(a)(2) relating to aggravated sexual assault of a child. III. The DSHS Child Abuse Reporting Form shall be used in the following manner: (1) to fax reports of abuse to DFPS or law enforcement and to document the report in the client record; (2) to document reports made by telephone; and (3) to document decisions not to report based on the existence of an affirmative defense. When making an online report to DFPS, contractor/providers may use a print-out of that report, rather than the Child Abuse Reporting Form, for documentation in the client record. All forms or online print-outs shall be retained by the contractor/provider in a manner required by the	A 133	The office administrator, physician and all staff will complete the Human Trafficking Prevention Task Force training course.	12-27-16

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A 133	Continued From page 6 program and are subject to DSHS monitoring. All forms or online print-outs concerning clients less than 14 years of age as described in item I. of this section will be examined during monitoring and must be readily available to the DSHS monitoring staff. A. The DSHS Child Abuse Reporting Form is an official DSHS form and may not be modified by the contractor/provider. B. Contractors/providers may add information to the bottom of the form below the DSHS required information. This is not considered modifying the form." In an interview on 09/13/16, staff members # 1 and 3 confirmed that there was no policy in place for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261 and that such suspected abuse was screened for and reported. The facility is did not had the DSHS Child Abuse Reporting Form available for use to screen for suspected sexual abuse. During a review of clinical records for 3 minor patients (patients #1 - #3), 3 of the 3 patients had not been screened for abuse. In an interview with staff #3 on the afternoon of 09/13/16, staff #3 confirmed that none of the minors had been screened for abuse. The above was verified in an interview with the Medical Director and Office Manager on the afternoon of 09/13/16.	A 133	The office administrator will provide a DSHS Child Abuse Reporting Form and complete training on human trafficking for physician and all staff members.	12-27-16
A 150	House Bill 416 Orientation/Training/Demonstrated Competency Employees of abortion facilities and ASCs who	A 150		

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A 150	Continued From page 7 perform 50 or more abortions in a 12-month period, must complete training on human trafficking. This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the facility staff failed to complete the required training on human trafficking. Findings were: During a review of personnel files for staff members #1 - #3, no documentation of training on human trafficking could be located. In an interview with staff #3 on the afternoon of 9-13-16, staff #3 confirmed that none of the 3 clinic staff had completed the required training on human trafficking. The above was verified in an interview with the Medical Director and Office Manager on the afternoon of 9-13-16.	A 150		
A 174	House Bill 15 Licensed Abortion Facility Administration An ASC that performs abortions must comply with Subchapter B, Chapter 171, HSC. This Requirement is not met as evidenced by: The facility failed to comply with Subchapter B, Chapter 171, Health and Safety Code. The Health and Safety Code, Title 2. Health, Subtitle H. Public Health Provisions, Chapter 171. Abortion, Subchapter A. General Provisions states in part,	A 174		

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A 174	Continued From page 8 "Sec. 171.012. VOLUNTARY AND INFORMED CONSENT. (a) Consent to an abortion is voluntary and informed only if: (1) the physician who is to perform the abortion informs the pregnant woman on whom the abortion is to be performed of: (A) the physician's name; (B) the particular medical risks associated with the particular abortion procedure to be employed, including, when medically accurate: (i) the risks of infection and hemorrhage; (ii) the potential danger to a subsequent pregnancy and of infertility; and (iii) the possibility of increased risk of breast cancer following an induced abortion and the natural protective effect of a completed pregnancy in avoiding breast cancer; (C) the probable gestational age of the unborn child at the time the abortion is to be performed; and (D) the medical risks associated with carrying the child to term; (2) the physician who is to perform the abortion or the physician's agent informs the pregnant woman that: (A) medical assistance benefits may be available for prenatal care, childbirth, and neonatal care; (B) the father is liable for assistance in the support of the child without regard to whether the father has offered to pay for the abortion; and (C) public and private agencies provide pregnancy prevention counseling and medical referrals for obtaining pregnancy prevention medications or devices, including emergency contraception for victims of rape or incest; (3) the physician who is to perform the abortion or the physician's agent: (A) provides the pregnant woman with the printed materials described by Section 171.014 < http://www.statutes.legis.state.tx.us/GetStatute.a	A 174		

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A 174	<p>Continued From page 9</p> <p>spx?Code=HS&Value=171.014&Date=7/18/2015 >; and</p> <p>(B) informs the pregnant woman that those materials:</p> <p>(i) have been provided by the Department of State Health Services;</p> <p>(ii) are accessible on an Internet website sponsored by the department;</p> <p>(iii) describe the unborn child and list agencies that offer alternatives to abortion; and</p> <p>(iv) include a list of agencies that offer sonogram services at no cost to the pregnant woman;</p> <p>(4) before any sedative or anesthesia is administered to the pregnant woman and at least 24 hours before the abortion or at least two hours before the abortion if the pregnant woman waives this requirement by certifying that she currently lives 100 miles or more from the nearest abortion provider that is a facility licensed under Chapter 245 or a facility that performs more than 50 abortions in any 12-month period:</p> <p>(A) the physician who is to perform the abortion or an agent of the physician who is also a sonographer certified by a national registry of medical sonographers performs a sonogram on the pregnant woman on whom the abortion is to be performed;</p> <p>(B) the physician who is to perform the abortion displays the sonogram images in a quality consistent with current medical practice in a manner that the pregnant woman may view them;</p> <p>(C) the physician who is to perform the abortion provides, in a manner understandable to a layperson, a verbal explanation of the results of the sonogram images, including a medical description of the dimensions of the embryo or fetus, the presence of cardiac activity, and the presence of external members and internal organs; and</p> <p>(D) the physician who is to perform the abortion</p>	A 174		

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A 174	Continued From page 10 or an agent of the physician who is also a sonographer certified by a national registry of medical sonographers makes audible the heart auscultation for the pregnant woman to hear, if present, in a quality consistent with current medical practice and provides, in a manner understandable to a layperson, a simultaneous verbal explanation of the heart auscultation;" Based on a review of documentation, personnel records and an interview with staff, patients did not receive a sonogram performed by a sonographer certified by a national registry of medical sonographers. Findings were: In a review of 12 clinical records, 12 of the 12 patients received their sonogram from a sonographer who was not certified by a national registry of medical sonographers. The personnel record for staff #3 contained no evidence of certification, and staff #3 confirmed that they were not certified by a national registry of medical sonographers. These findings were confirmed on 09/13/16 with staff members #1 and 3.	A 174	The Medical Director (Physician) will perform all sonograms.	12-27-16
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	<p>Continued From page 11</p> <p>This Requirement is not met as evidenced by: Based on tour and interview, the facility failed to ensure a safe and sanitary environment, properly maintained to protect the health and safety of patients and staff at all times.</p> <p>Findings included:</p> <p>During a tour of the facility on 09/13/16 the following infection control and safety issues were noted:</p> <p>* Staff #3 wore long (approximately 1/2"), artificial nails adorned with small jewels and decorations, creating a surface similar to chipped nail polish with multiple areas for bacteria to become lodged.</p> <p>According to the CDC Morbidity and Mortality Weekly Report, October 25, 2002 / Vol. 51 / No. RR-16:</p> <p>" Studies have documented that subungual areas of the hand harbor high concentrations of bacteria, most frequently coagulase-negative staphylococci, gram-negative rods (including Pseudomonas spp.), Corynebacteria, and yeasts (14,342,343). Freshly applied nail polish does not increase the number of bacteria recovered from periungual skin, but chipped nail polish may support the growth of larger numbers of organisms on fingernails (344,345). Even after careful handwashing or the use of surgical scrubs, personnel often harbor substantial numbers of potential pathogens in the subungual spaces (346-348) ...HCWs who wear artificial nails are more likely to harbor gram-negative pathogens on their fingertips than are those who have natural nails, both before and after</p>	A 197	<p>The Medical Director will have all office staff members remove any artificial nails.</p>	12-27-16

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A 197	Continued From page 12 handwashing (347-349). " * Tears to the vinyl covering of examination tables were observed in Rooms 1 and 3. In Room # 1 the bottom corners of the table were covered in duct tape (approximate 3 X 3 inch areas) and a 6 inch uncovered tear was observed in the vinyl at the foot of the table. In Room # 3 a small 1/2 inch tear was observed at in the vinyl of the foot rest of the examination table. The tears prevents effective cleaning and presents the potential for contamination. * In Room # 1 a dead cockroach was observed in the bottom drawer of the examination table. * In Room # 3 the sonogram machine was observed to have tape covering the control panel and cracks were visible in the control panel itself, preventing effective cleaning and increase risk for bacterial growth. * In the sterilization area of the facility 3 packaged and sterilized scissors were observed in the closed position. 1 pack of sterilized surgical instruments also contained 1 ringed forceps that was observed in the closed position. It could not be determined that these surfaces were appropriately cleaned. When instruments are closed, the sterilizing agent cannot penetrate all surfaces to ensure complete sterilization of all surfaces of the instruments. The Centers for Disease Control and Prevention (CDC) article, GUIDELINE FOR DISINFECTION AND STERILIZATION IN HEALTHCARE FACILITIES, 2008, by William A. Rutala, Ph.D., M.P.H., David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC), found at: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf , states on page 74 that hinged instruments and instruments that close should be opened during the process of sterilization.	A 197	The Medical Director will have examination tables in room 1 and 3 reupholstered. The Medical Director will have the facility fumigated and completely wiped down with dispatch disinfectant and free of any debree and insects. The office administrator will provide a daily check list of all the rooms being free of debree and insects. The Medical Director will provide a new control panel cover for ultrasound machine in room #3 the Aloka 620. The office administrator will provide a daily log check list for all instruments before packaging to assure all instruments are open and in proper position before being autoclaved and will be monitored by Medical Director.	12-27-16 12-27-16 12-27-16 12-27-16

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A 197	Continued From page 13 * A drawer in Room #1 contained 6 of 19 chlamydia culture tubes that had expired but were still available for use. * A drawer in Room #1 contained 1 of 1 general culture tube that had expired but was available for use. The above finding were confirmed in an interview with staff members #1 and 3 on 09/13/16 during the tour of the facility.	A 197	The Office Administrator will provide a daily check list for any expired items that will be monitored by Medical Director.	12-27-16
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 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 review of documentation and interview, the facility failed to have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Findings included: In an interview on 09/13/16 staff members #1 and 3 confirmed that the facility does not have a written protocol for emergency evacuation for fire	A 200	The office administrator will provide an Emergency Protocol Evacuation for fire and other disasters with an evacuation plan.	12-27-16

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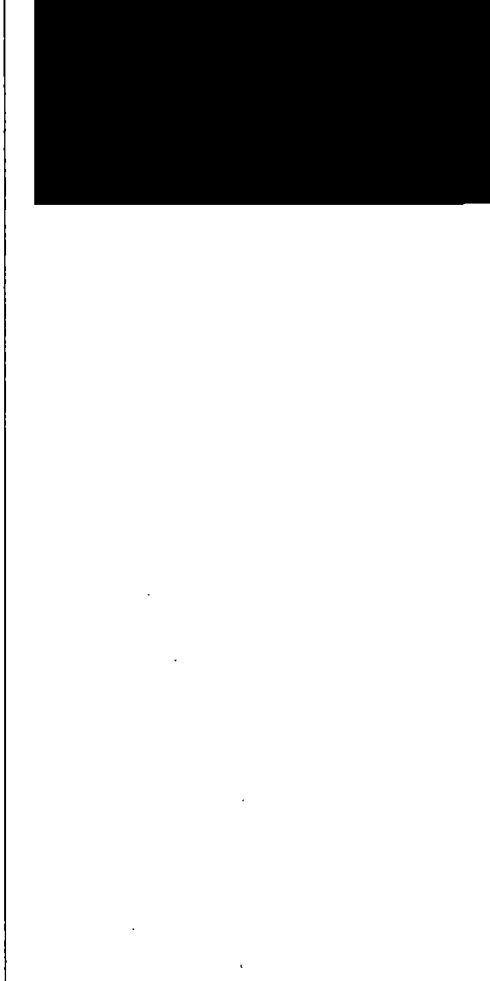
NAME OF PROVIDER OR SUPPLIER WOMEN'S CENTER HOUSTON	STREET ADDRESS, CITY, STATE, ZIP CODE 8200 WEDNESBURY LANE, SUITE 230 HOUSTON, TX 77074
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A 200	Continued From page 14 and other disasters tailored to the facility's geographic location.	A 200		
A 201	<p>TAC 139.48(1)(E)(F) Physical & Environmental Requirements</p> <p>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; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food Establishments);</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. Failure to do so increases the risk of harm to patients.</p> <p>Findings were:</p> <p>During a tour of the facility on 09/13/16, the unsecured cleaning solutions and compounds (including disinfectant spray, germicidal wipes, and all-purpose spray cleaner and bleach) were observed throughout the facility in cabinets and on shelves.</p> <p>The above was confirmed in an interview with staff #1 on 09/13/16 during a tour of the facility.</p>	A 201	All hazardous cleaning solutions and compounds will be removed from all rooms and be stored in a secure manner(cabinet with lock).Only the Medical Director will have access to.	12-27-16

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A 249	Continued From page 15	A 249		
A 249	<p>TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards</p> <p>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.</p> <p>(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.</p> <p>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.</p> <p>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.</p> <p>(iv) Storage of supplies shall be in areas that are designated for storage.</p> <p>This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to store peel pouches in a manner that prevented the sterility from being compromised.</p> <p>Findings included:</p> <p>During a tour of the facility on 09/13/16, multiple peel pouches were stored in a plastic bin with drawers in the sterilization room. In one of four drawers, multiple peel packages of sterilized instruments were observed with water stains/water damaged packaging. Water was also present to touch on the peel packages in this drawer. The presence of water and water stains/damage to the sterilized instruments presents a risk for bacterial growth and contamination, compromising there sterility of</p>	A 249	<p>The office administrator will provide a daily check list for damaged packaging. All packages must be observed before use and be free of any stains and no water damages. Medical Director will monitor packages to assure all sterilized item shall be stored in well ventilated and controlled temperature and humidity area. Also assure packaging is not crushed, bent, compressed or punctured. All intstruments will be in areas that are designated for storage.</p>	12-27-16

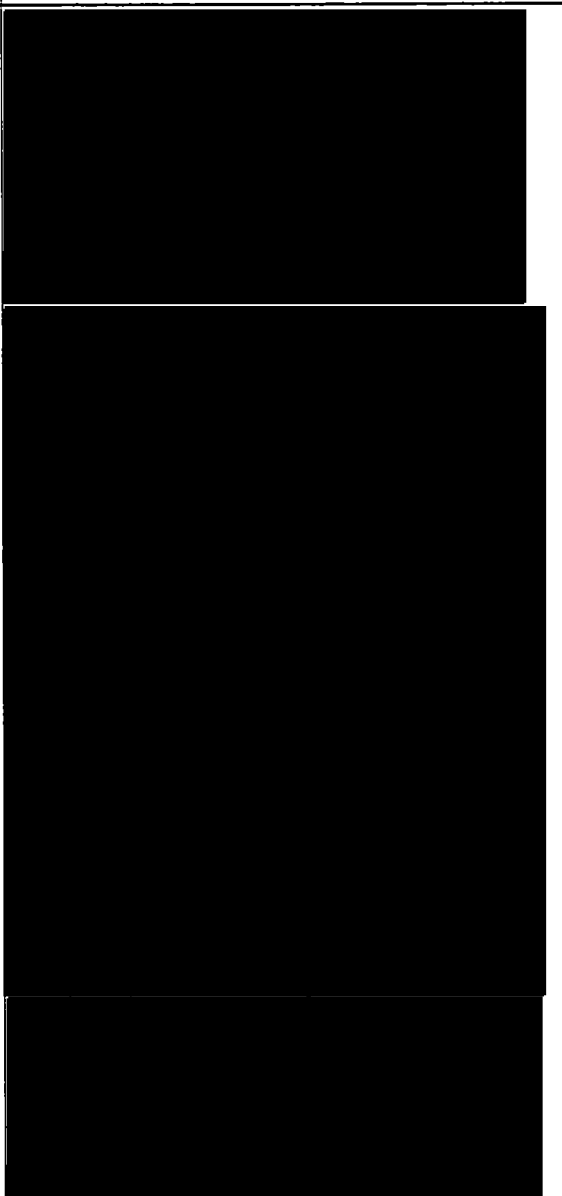
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A 249	Continued From page 16 these instruments. An interview with Staff #1 on 09/13/16, above findings were confirmed.	A 249		
A 260		A 260		

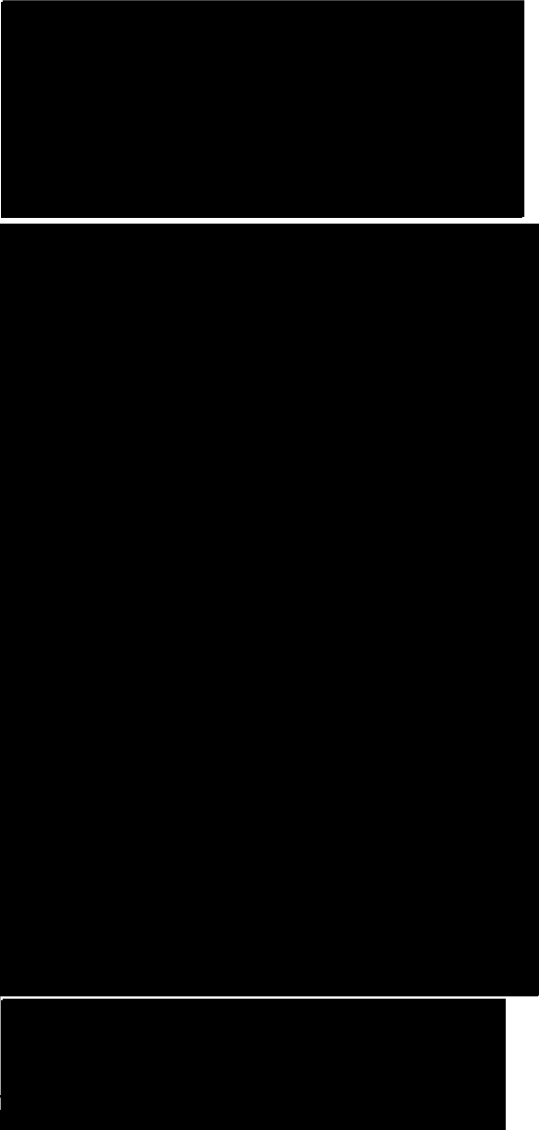
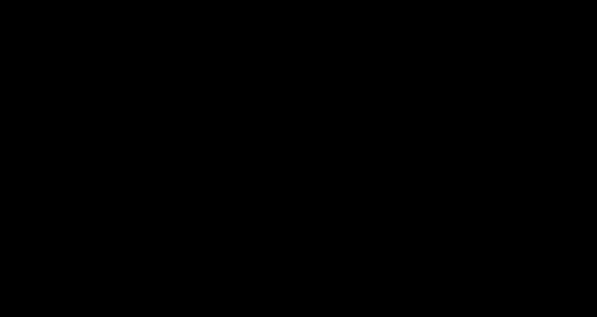
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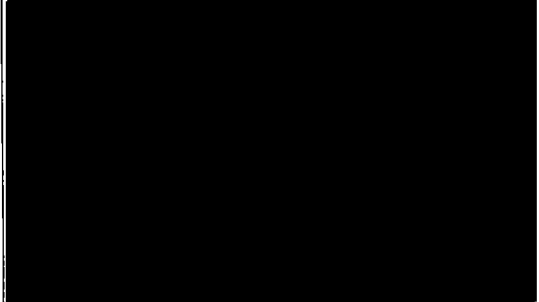
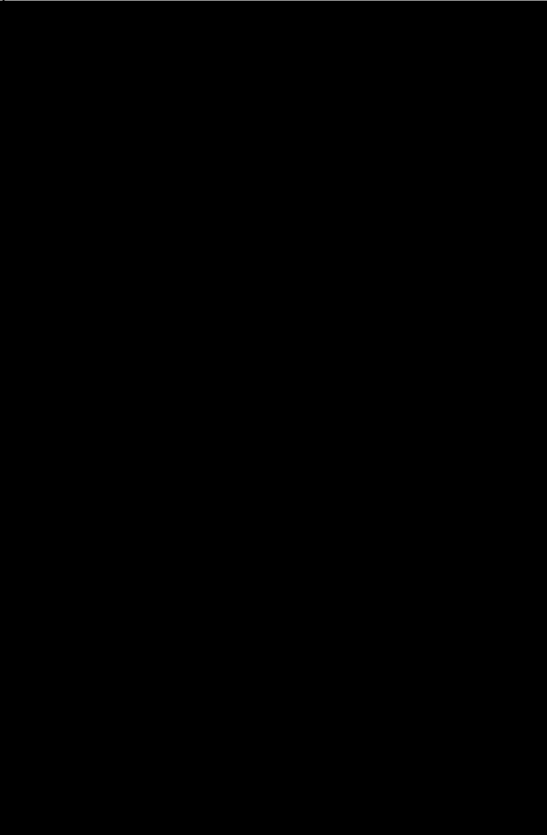
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A 260		A 260		

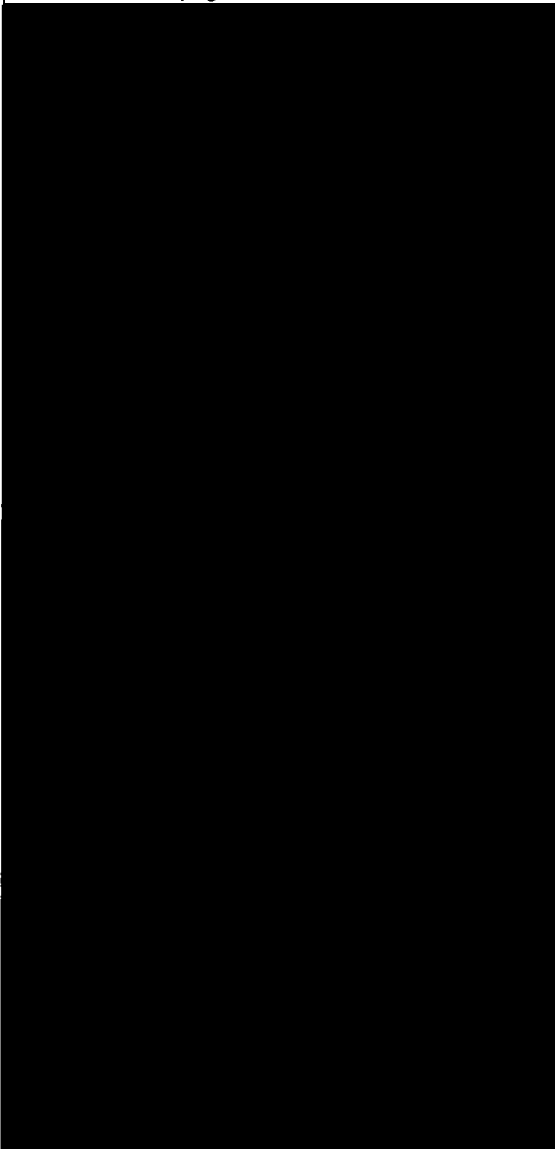
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A 260	Continued From page 18 	A 260	

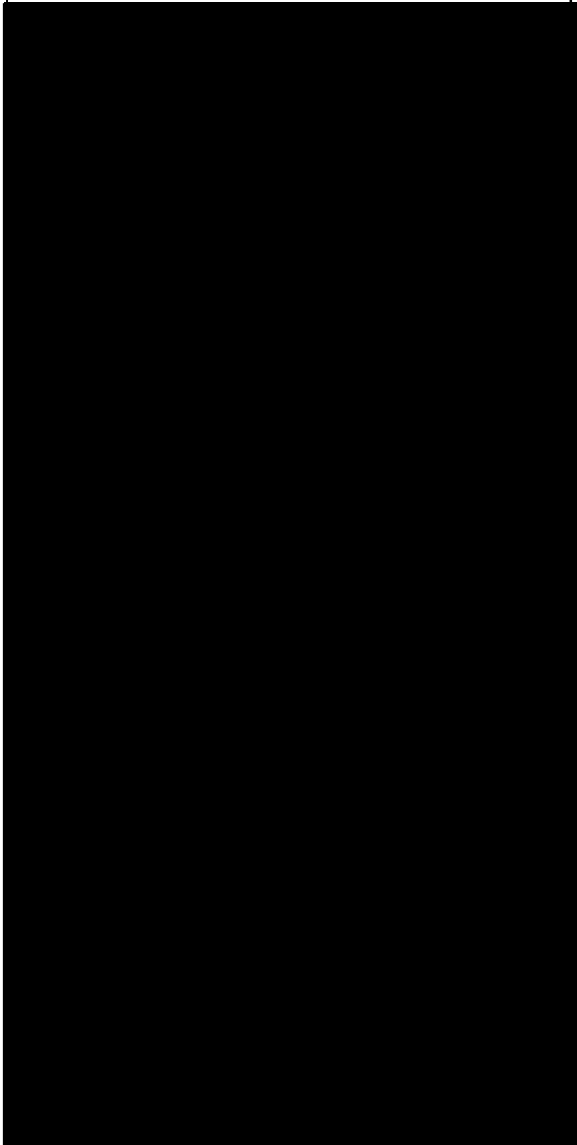
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A 260	Continued From page 19 	A 260		
A 338		A 338		

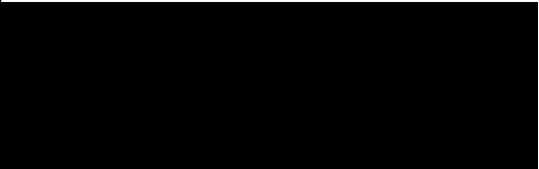
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A 338	Continued From page 20 	A 338		

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A 338	Continued From page 21 	A 338		

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A 338	Continued From page 22 	A 338		
A 362	TAC 139.57(a)(2)(A)(B)(C)(D)(3) Discharge and Follow-up Referrals (a) A licensed abortion facility shall develop and implement written discharge instructions which shall include: (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: (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; (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; (C) assurance that the responding individual shall be a physician, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse; and (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 (3) information concerning the need for a	A 362	The office administrator will provide a form for each patient with a telephone number which patient may reach the physician or healthcare personnel employed by the physician available 24hours a day 7 days a week. The office administrator will provide written discharge instructions which will include the name and telephone number of the nearest hospital to the patient's home address.	12-27-16 12-27-16

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A 362	Continued From page 23 post-abortion examination. This Requirement is not met as evidenced by: Based on a review of medical records and interview, the facility failed to implement written discharge instructions which included 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. Findings included: 12 of 12 patient medical records had discharge instructions which did not included the name of nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated. Also no telephone number was provided for the nearest hospital. In an interview on 09/13/16, staff members #1 and 3 verified the above findings.	A 362		