

CASE NO. 1068172086

IN THE MATTER OF

HOUSTON WOMEN'S CLINIC

HOUSTON, TEXAS

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BEFORE THE

**DEPARTMENT OF
STATE HEALTH SERVICES**

AUSTIN, TEXAS

AGREED ORDER FOR PAYMENT

I. JURISDICTION

The Department of State Health Services (Department) is authorized to enforce the Health and Safety Code (HSC), Chapter 245 (Act), and Title 25 of the Texas Administrative Code (TAC), Chapter 139 (Rules), relating to the licensing and regulation of Abortion Facilities in Texas.

II. RESPONDENT

Houston Women's Clinic, 4820 San Jacinto, Houston, TX 77004 is licensed by the Department as an Abortion Facility, License No. 007326, and is subject to the Act and Rules.

III. FACTS

On or about August 16, 2016, the Department conducted a re-licensure survey of the Respondent. The purpose of the survey was to determine Respondent's compliance with the Act and the Rules. As a result of the survey, the Department alleged the Respondent engaged in the conduct as more specifically described in the Department's February 7, 2017, Notice of Violation (Notice) which is adopted and incorporated in this Agreed Order (Order).

IV. NOTICE

In the Notice, Respondent was informed of the Department's intent to assess an Administrative Penalty in the amount of \$20,300.00.

V. RESPONSE

By response dated February 24, 2017, Respondent replied to the Notice by admitting the facts and violations alleged, agreeing to the Administrative Penalty proposed by the Department and to issuance of this Order, and sending the Department a check in the agreed amount of \$20,300.00, which was posted by the Department on February 28, 2017 (Remittance No. M271106 000 P).

VI. SETTLEMENT

Respondent, in its response, agreed to the Department's issuance of this Agreed Order, with its findings, imposition and payment of the Administrative Penalty, as proposed, to fully resolve and settle, as between the parties, the allegations of the Notice, as set forth and ordered herein.

VII. ACCEPTANCE OF ADMINISTRATIVE PENALTY

This Order is made pursuant to Chapter 2001 of the Texas Government Code §2001.056(2), and the procedural rules adopted by the Department. This Order memorializes Respondent's acceptance of payment of the \$20,300.00 Administrative Penalty for all violations contained in the Notice as described in "III. Facts" and "IV. Notice" of this Order.

A. WAIVER OF APPEAL

In exchange for Respondent's payment of the penalty, and the execution of this Order, Respondent waives the right to a hearing or an appeal regarding the Department findings, assessment of the proposed administrative penalty and the Department's disposition of this case through the Department's issuance of an Order.

B. NO WAIVER WITH REGARD TO FUTURE VIOLATIONS

The Department does not waive the right to enforce this Order or to prosecute any future violations that Respondent may commit and shall consider this Order in the processing of any future enforcement action(s).

NOW THEREFORE, IT IS ORDERED that Respondent paid an Administrative Penalty in the amount of \$20,300.00, which the Department posted on March 1, 2017. Respondent shall henceforth comply with all applicable laws, rules and regulations. Failure to comply shall result in additional enforcement action.

Ordered this 30th day of March, 2017.



Jon Huss
Interim Associate Commissioner
Division for Regulatory Services



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DR. JOHN W. HELLERSTEDT
COMMISSIONER

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February 7, 2017

Certified Mail Number: 7011 0470 0003 0321 2018
and First Class Mail Service

Richard C. Yount Jr., Registered Agent
Houston Women's Clinic, LLC
4800 Interfirst Plaza, Ste 1100
Houston, TX, 77002

Certified Mail Number: 7011 0470 0003 0321 2025
and First Class Mail Service

Bernard Rosenfeld, Owner
Houston Women's Clinic, LLC
4820 San Jacinto Street
Houston, TX, 77004

**Re: Notice of Violation (Notice), Houston Women's Clinic, Abortion Facility, License #007326,
Case #1068172086, Docket #A26811-519-2017**

Dear Mr. Yount:

The Department of State Health Services (Department) has reviewed documents and evidence related to a re-licensure survey of Houston Women's Clinic (Respondent) located at 4820 San Jacinto, Houston TX 77004 (Facility) conducted on or about August 16, 2016.

As a result of that review, the Department proposes to impose an administrative penalty in the amount of \$20,300.00 against the Facility pursuant to its authority under Chapter 245 of the Texas Health and Safety Code (HSC) and Title 25 of the Texas Administrative Code (TAC) Chapter 139 (Rules).

The proposed action is based upon the following allegations (names of persons identified by initials or numbers will be provided upon request if permitted by law):

- 1. The Facility failed to meet at least quarterly to identify issues with respect to which quality assurance activities are necessary, to wit :**

The Facility's records revealed there was no quarterly meeting held during April, May, or June of 2015 to determine if the facility had quality issues regarding patients that needed to be addressed. This is in violation of 25 TAC §139.8(c), which states:

139.8 Quality Assurance

(c) Frequency of QA committee meetings. The QA committee, by consensus, shall meet at least quarterly to identify issues with respect to which quality assurance activities are necessary.

An administrative penalty in the amount of \$350.00 is proposed for this rule violation.

2. The Facility failed to make available current/accurate information for visitors and patients on how to report complaints, to wit:

The Facility's policy on reporting requirements revealed an incorrect telephone number for reporting complaints relating to the Facility. This is in violation of 25 TAC §139.41(a)(1)(H) and (I), which state:

§139.41 Policy Development and Review

(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:

(1) administrative policies governing the administration of the facility, covering at a minimum:

(H) reporting requirements; and

(I) procedures for the resolution of complaints regarding care or services rendered by licensed health professionals and other members of the facility staff, including contract services or staff....

An administrative penalty in the amount of \$100.00 is proposed for this rule violation.

3. The Facility failed to develop or implement a post-procedure infection monitoring policy, to wit:

The Facility failed to develop any policies regarding post-procedure patient follow-up and monitoring of post-procedure infection for patients and did not have records of making any post-procedure follow-up attempts for 11 patients. This is in violation of 25 TAC §139.41(a)(2)(G) and (I), which state:

§139.41 Policy Development and Review

(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:

(2) clinical policies governing medical and clinical practices and procedures of the facility, covering at a minimum:

(G) clinical records;

(I) monitoring post-procedure infection(s).

An administrative penalty in the amount of \$3,850.00 (\$350 x 11 patients) is proposed for this rule violation.

4. The Facility failed to conduct annual evaluations and infection control training, to wit:

The Facility's record review revealed lack of annual evaluations conducted and lack of infection control training for six staff members, contrary to its own policy. This is in violation of 25 TAC §139.43(2)-(5), which state:

§139.43 Personnel Policies

The licensee shall develop, implement and enforce policies which shall govern all personnel staffed by the facility using the following minimum criteria:

(2) a requirement for orientation of all employees, volunteers, students and contractors to the policies and objectives of the facility and participation by all personnel in employee training specific to their job;

(3) job-related training for each position;

(4) a requirement for an annual evaluation of employee performance;

(5) in-service and continuing education requirements;

An administrative penalty in the amount of \$2,100.00 (\$350 x 6 staff) is proposed for this rule violation.

5. The Facility failed to maintain documentation of required laboratory testing and vaccinations of staff, to wit:

The Facility's records did not show that Hepatitis B titers were drawn or vaccinations were given, or that Tuberculosis testing was conducted, for five staff members. This is in violation of 25 TAC §139.45(3), which states:

§139.45 Personnel Records.

An individual personnel record shall be maintained on each person employed by the licensed abortion facility which shall include, but not be limited to, the following:

- (3) clinical laboratory tests results and vaccinations if required by law (e.g., Mycobacterium tuberculosis, hepatitis B virus);

An administrative penalty in the amount of \$1,750.00 (\$350 x 5 staff) is proposed for this rule violation.

6. The Facility failed to provide a safe and sanitary environment to protect the health and safety of patients and staff, to wit:

An inspection found twenty-two (22) instances of sterilization, sanitation, and safety issues. This is in violation of 25 TAC §139.48(1)(A), which states:

§139.48 Physical and 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;

An administrative penalty in the amount of \$7,700 (\$350 x 22 instances) is proposed for this rule violation.

7. The Facility failed to enforce infection control policies to minimize the transmission of infection, to wit:

The facility failed to safeguard against the proliferation of infection in three (3) procedure rooms. This is in violation of 25 TAC §139.49(a), which states:

§139.49 Infection Control Standards

- (a) Written policies. A licensed abortion facility shall develop, implement, and enforce infection control policies and procedures to minimize the transmission of post-procedure infections. These policies shall include, but not be limited to, the prevention of the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Mycobacterium tuberculosis (TB), and Streptococcus species (S. spp.); educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies.

An administrative penalty in the amount of \$1,050 (\$350 x 3 rooms) is proposed for this rule violation.

8. The Facility failed to properly package and document instruments to be sterilized, to wit:

The Facility failed to document on the instrument packages the date and time of sterilizing, sterilizing load number, and the identification of the autoclave used and failed to properly seal the packaging. This is in violation of 25 TAC §139.49(d)(5)(D)(i)-(ii), which state:

§139.49 Infection Control Standards

(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this subsection to provide effective sterilization measures.

(D) Packaging.

(i) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall not exceed 17 pounds.

(ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave.

An administrative penalty in the amount of \$350.00 is proposed for this rule violation.

9. The Facility failed to use external chemical indicators, to wit:

The Facility failed to use external chemical indicators in peel pouches stored in a plastic container and in peel pouches that were removed from the autoclave and also failed to adhere to its own policy concerning sterilization indicators. This is in violation of 25 TAC §139.49(d)(5)(E)(i)-(ii), which state:

§139.49 Infection Control Standards

(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this subsection to provide effective sterilization measures.

(E) External chemical indicators.

(i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process.

(ii) The indicator results shall be interpreted according to the manufacturer's written instructions and indicator reaction specifications.

An administrative penalty in the amount of \$350.00 is proposed for this rule violation.

10. The Facility failed to follow manufacturer's written instructions in sterilizing instruments, to wit:

The Facility stacked peel pouches on top of other peel pouches in the sterilizer, contrary to the manufacturer's instructions. This is in violation of 25 TAC §139.49(d)(5)(G)(i)-(ii), which states:

§139.49 Infection Control Standards

(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this subsection to provide effective sterilization measures.

(G) Sterilizers.

(i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.

(ii) Other sterilizers shall be used in accordance with the manufacturer's instructions.

An administrative penalty in the amount of \$350 is proposed for this rule violation.

11. The Facility failed to provide and ensure proper and adequate storage of sterilized items, to wit:

The Facility failed to provide a designated storage area for sterilized instruments and also failed to store peel pouches in a position that was free of being crushed, bent, compressed or punctured. This is in violation of 25 TAC §139.49(d)(5)(J)(i)-(iv), which state:

§139.49 Infection Control Standards

(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this subsection to provide effective sterilization measures.

(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.

(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.

(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.

(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.

(iv) Storage of supplies shall be in areas that are designated for storage.

An administrative penalty in the amount of \$350.00 is proposed for this rule violation.

12. The Facility failed to document and maintain clinical records accurately, to wit:

The facility failed to document the date and provide a legible staff member signature for eleven (11) patient records reviewed. This is in violation of 25 TAC §139.55 (b) (6) which states:

§139.55 Clinical Records

(b) A licensed abortion facility shall establish and maintain a clinical record for each patient. A licensed abortion facility shall maintain the record to assure that the care and services provided to each patient is completely and accurately documented, and readily and systematically organized to facilitate the compilation and retrieval of information. Information required for the annual abortion report shall be readily retrievable from the clinical record.

(6) A facility shall maintain clinical records in their original state. Each entry shall be accurate, dated with the date of entry, and signed by the individual making the entry. Correction fluid or tape shall not be used in the record. Corrections shall be made by striking through the error with a single line, and shall include the date the correction was made and the initials of the person making the correction.

An administrative penalty in the amount of \$350.00 is proposed for this rule violation.

13. The Facility failed to develop and implement policies and procedures for patient post-procedure follow-up, to wit:

The Facility referred a patient who reported post-abortion complications to an emergency room and did not attempt to further inquire about her condition or confirm that she sought treatment. The Facility had no policy or process for patient follow-up and monitoring of post-procedure infections. This is in violation of 25 TAC §139.57(c)(1) and (2), which state:

§139.57 Discharge and Follow-up Referrals

(c) The facility shall develop and implement written policies and procedures for:

(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:

(A) the facility to maintain a written system of documentation of patients who report post-abortion complications within 14 days of the procedure date;

(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

(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

(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.

An administrative penalty in the amount of \$350 is proposed for this rule violation.

14. The Facility failed to ensure that schedule II – V drugs were properly secured, to wit:

The Facility had no policy concerning the security of scheduled narcotics and failed to ensure schedule II – V narcotic medications were kept locked within a secure area where unauthorized personnel and patients will not have access, specifically:

- (1) A procedure room had 24 unlabeled and pre-filled syringes containing Valium, Stadol, Romazicon, and Chlorprocaine stored in an unlocked cabinet underneath the surgical suction machine.
- (2) The medication area, located along a common hallway where patients await procedures, has no door and contained a portable lockbox which contained pre-drawn syringes of Valium, Ativan and Stadol that was left unsecured on the countertop.

This is in violation of 25 TAC §139.60 (a) which states:

§139.60 Other State and Federal Compliance Requirements

(a) A licensed abortion facility shall be in compliance with all state and federal laws pertaining to handling of drugs.

An administrative penalty in the amount of \$1,300.00 (\$650 x 2 rooms) is proposed for this rule violation.

In accordance with Government Code Section 2001.054(c), you have the right to show compliance with all requirements of law prior to final action by the Department. **Within 20 calendar days following the day you receive this notice, you may:**

- 1) Admit the allegations and accept the Department's determination to impose an Administrative Penalty in the amount of \$20,300.00. Remit the recommended penalty amount of \$20,300.00 by cashier's check, money order, or company check made payable to the Department of State Health Services, with a notation of: *Deposit in Budget #ZZ156, Fund #170*, and return the enclosed Response to Notice form, with the first box checked. Please be sure to sign and date the form; or
- 2) Submit a written request for an informal conference and a hearing (if necessary), regarding the occurrence of the alleged violations, the amount of the penalties, or both; or,
- 3) Submit a written request for a contested case hearing to be held at the State Office of Administrative Hearings regarding the occurrence of the alleged violations, the amount of the penalty, or both.

Please use the attached **RESPONSE TO NOTICE** form to notify the Department of which option you have selected.

FAILURE TO RESPOND TO THIS NOTICE WITHIN 20 CALENDAR DAYS FROM THE DATE YOU RECEIVE THIS LETTER WILL BE CONSIDERED A WAIVER OF YOUR RIGHT TO A HEARING, THE ALLEGATIONS IN THIS NOTICE WILL BE DEEMED TRUE, AND THE DEPARTMENT WILL ASSESS THE ADMINISTRATIVE PENALTIES BY DEFAULT.

If you have any questions regarding this proposal, please contact me at (512) 834-6665, ext. 2092.

Sincerely,



Charles Burkhalter, BAS
Program Specialist
Enforcement Unit
Division for Regulatory Services

Enclosure