



TO: Health and Human Services Commission
Executive Council

DATE: December 6, 2018

FROM: Kristi Jordan, Director, Health Care Quality,
Regulatory Services Division

AGENDA ITEM: 2.t

SUBJECT: Abortion Facility Licensing Procedures and Enforcement

BACKGROUND: Federal Legislative Other: Program Initiative

The rule amendments are necessary to update the existing abortion facility initial licensure procedures and requirements when an initial abortion facility application is received and to require a licensed abortion facility to submit an initial application upon change of physical location. The rules became effective June 28, 2009, and require updating due to the Health and Human Services Commission assuming the duties of the Department of State Health Services on September 1, 2017. Title 25 Texas Administrative Code Chapter 139 implements Texas Health and Safety Code Chapter 245.

The proposal of §§139.21 - 139.25 and 139.31 amends and updates the licensing procedures when a licensed abortion facility requests a change of physical location and amends the inspection procedures for an abortion facility when an application is received by the commission.

ISSUES AND ALTERNATIVES:

Rules addressing abortion traditionally receive considerable public interest.

STAKEHOLDER INVOLVEMENT:

The proposed rule amendments will be available for public comment when the rules are published in the *Texas Register*.

FISCAL IMPACT:

Yes

There will be fiscal implications to state government as a result of enforcing and administering the sections as proposed. The rules are expected to increase revenue to the State due to collection of licensing fees for licensed

facilities where a physical location will occur. There is insufficient data to estimate the net change in revenue at this time.

SERVICES IMPACT STATEMENT:

The public will benefit from the rule amendments because the proposing and enforcing of these rules will provide increased clarity and consistency in enforcement of existing rules and to more accurately reflect existing statutes.

RULE DEVELOPMENT SCHEDULE:

December 2018	Publish proposed rules in <i>Texas Register</i>
December 6, 2018	Present to HHSC Executive Council
March 2019	Publish adopted rules in <i>Texas Register</i>
March 2019	Effective date

PROPOSED PREAMBLE

The Texas Health and Human Services Commission (HHSC) proposes amendments to §139.21, concerning General Requirements for Licensure; §139.22, concerning Fees; 139.23, concerning Application Procedures and Issuance of Licenses; §139.24, concerning Change of Ownership or Services, and Closure of a Licensed Abortion Facility; §139.25, concerning Time Periods for Processing and Issuing a License; and §139.31, concerning On-Site Inspections and Complaint Investigations of a Licensed Abortion Facility.

BACKGROUND AND PURPOSE

The proposed rule amendments are necessary to update existing abortion facility initial licensing requirements to require a pre-licensing inspection and to require an initial license application when a licensed abortion facility seeks to change its physical location. The current existing rules became effective June 28, 2009, and require updating due to HHSC assuming the duties of the Department of State Health Services (Department) on September 1, 2017. Title 25 of the Texas Administrative Code Chapter 139 implements the Texas Health and Safety Code, Chapter 245.

SECTION-BY-SECTION SUMMARY

Proposed §139.21(8) amends the licensure requirement to reflect that an abortion facility's license shall not be transferred from one physical location to another physical location.

Proposed §139.22 amends the initial application requirements to include an initial application and fee for abortion facilities changing their physical location and updates text for clarity and consistency. Additionally, the amendment includes the replacement of "department" with "commission" and "Department of State Health Services" with "Texas Health and Human Services Commission."

Proposed §139.23 amends the initial application licensing procedures for an abortion facility to require a new application upon a change of physical location and to include a pre-licensing inspection of the physical location from which the abortion facility will operate. Additionally, the amendment updates text for clarity and consistency and replacing "department" with "commission."

Proposed §139.24 amends the rule title, adds a new subsection (b) to include the provisions for "Change of Physical Location" by a licensed abortion facility, which describes the necessary steps and requirements once

the commission is notified of this request, and updates the rule text for consistency and clarity. Additionally, the amendment includes the replacement of "department" with "commission."

Proposed §139.25 amends the time periods and issuance of a license to an abortion facility to include a request for "Change of Physical Location" and updates the rule text for consistency and clarity. Additionally, the amendment includes the replacement of "department" with "commission."

Proposed §139.31 amends the inspection procedures to include an announced on-site inspection for abortion facilities once an initial application for licensure has been submitted to the commission. Additionally, the amendment includes the replacement of "department" with "commission" and updates the mailing address for the commission's Health Facility Licensing Compliance Group.

FISCAL NOTE

Greta Rymal, Deputy Executive Commissioner for Financial Services, has determined that for each year of the first five years that the rules, as amended, will be in effect, there may be fiscal implications to state government as a result of enforcing and administering the sections as proposed. These rules are expected to increase revenue to the State due to the collection of up to \$5,000 for each initial application submitted to request a physical location change. HHSC lacks sufficient data to estimate any additional revenues from the new licensing fee. In addition, the State may incur costs to conduct the on-site pre-licensing inspections. HHSC assumes the additional staff time and travel costs can be absorbed within existing resources.

There will be no effect on local government.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years that the sections will be in effect:

- (1) the proposed rules will not create or eliminate a government program;
- (2) implementation of the proposed rules will not affect the number of employee positions;
- (3) implementation of the proposed rules will not require an increase or decrease in future legislative appropriations;
- (4) the proposed rules may affect fees paid to the agency;

- (5) the proposed rules do not create new rules;
- (6) the proposed rules expand existing rules;
- (7) the proposed rules will not change the number of individuals subject to the rules; and
- (8) the effect of the proposed rules on the state's economy cannot be determined at this time.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Ms. Rymal has determined that there may be an adverse economic effect on small businesses or micro-businesses as the rules are proposed. The proposed rules will require existing licensed abortion facilities to submit an application and fee upon a physical location change. HHSC lacks sufficient information to determine if one or more of the fifteen (15) licensed abortion facilities would be considered a small or micro-business. None of the existing licensed abortion facilities would be considered a rural community.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are anticipated economic costs to person who are required to comply with the rules as proposed. For a change of physical location, a licensed abortion facility will be required to submit an initial licensing application and pay a fee of \$5,000.

There is no anticipated negative impact on local employment.

COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of this state.

PUBLIC BENEFIT

David Kostroun, HHSC Deputy Executive Commissioner of Regulatory Services, has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of adopting and enforcing these rules will be increased conformity with existing statutes.

REGULATORY ANALYSIS

HHSC has determined that this proposal is not a "major environmental rule" as defined by Texas Government Code, §2001.0225. "Major environmental

rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

HHSC has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to the Health and Human Services Commission, Mail Code 1065, P.O. Box 13247, Austin, Texas 78711, or by email to chapter139comments@hhsc.state.tx.us. Please specify "Comments on Chapter 139 Proposed Rules 19R005" in the subject line. Comments are accepted for 30 days following publication of the proposal in the *Texas Register*. If the last day to submit comments falls on a weekend or holiday, comments that are postmarked, shipped, or emailed before midnight on the following business day will be accepted.

STATUTORY AUTHORITY

The rule amendments are authorized by the Texas Health and Safety Code, Chapter 245.

Texas Government Code, §531.0055, authorizes the Executive Commissioner to adopt rules and policies necessary for the operation and provision of health and human services.

The rules implement Texas Health and Safety Code, Chapters 171 and 245; and Texas Government Code, Chapter 531.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 139 ABORTION FACILITY REPORTING AND LICENSING
SUBCHAPTER B LICENSING PROCEDURES

§139.21. General Requirements for Licensure.

An applicant for an abortion facility license shall meet the following requirements.

(1) - (7) (No change.)

(8) An abortion facility license shall not be transferred or assigned from one person to another person or from one physical location to another physical location.

(9) (No change.)

§139.22. Fees.

(a) Fees for [~~two-year renewals for~~] an abortion facility license for all initial, change of ownership, change of physical location, and renewal applications are \$5,000. [~~as follows:~~]

[~~(1) initial license fee--\$5,000;~~]

[~~(2) renewal license fee--\$5,000; and~~]

[~~(3) change of ownership license fee--\$5,000.~~]

(b) The commission [~~department~~] shall not consider an application as officially submitted until the applicant pays the applicable licensing fee. The fee shall accompany the application form.

(c) A license fee paid to the commission [~~department~~] is not refundable.

(d) Any remittance submitted to the commission [~~department~~] in payment of a required license fee shall be in the form of a certified check, money order, or personal check made payable to the Texas Health and Human Services Commission [~~Department of State Health Services~~].

(e) For all applications [~~and renewal applications~~], the commission [~~department~~] is authorized to collect subscription and convenience fees, in amounts determined by the TexasOnline Authority, to recover costs

associated with application and renewal application processing through TexasOnline, in accordance with Government Code, §2054.111.

(f) The commission [~~department~~] may make periodic reviews of its license fee schedule to ensure that the fees imposed are in amounts reasonable and necessary to defray the cost to the commission [~~department~~] of administering the Act.

(g) The commission [~~department~~] shall impose [~~assess~~] an annual assessment [~~fee~~] as follows.

(1) In addition to application fees [~~for initial, renewal, and change of ownership license fees~~], the commission shall impose on each facility an annual assessment [~~fee per year shall be imposed by the department~~] in amounts reasonable and necessary to defray costs.

(2) The [~~amount of the one-time per year~~] annual assessment [~~fee~~] shall fall into one of three categories based on the facility's three-year history: [~~be determined by the department on an annual basis.~~]

[~~(3) Fees shall be divided into three categories based on a three-year history:~~]

(A) Facilities for which the annual average of [~~per year of the previous three years~~] reported abortions is [~~equals~~] less than 1,000 or facilities applying for an initial license;

(B) Facilities for which the annual average of [~~per year of the previous three years~~] reported abortions is from [~~equals~~] 1,000 to [~~-~~] 2,999;

(C) Facilities for which the annual average of [~~per year of the previous three years~~] reported abortions is [~~equals~~] 3,000 or more.

(3) [~~(4)~~] Facilities identified in each category shall be assessed a proportionate share of the costs.

(4) [~~(5)~~] Facilities applying for [~~Licensees receiving~~] an initial license shall submit the assessment [~~be assessed the least of the three fees in effect at the time of application for an initial or change of ownership license. The additional annual assessment fee is due~~] at the same time as the application fee.

(5) [~~(6)~~] The commission [~~department~~] shall notify each licensee of the amount of the [~~assessed for the~~] annual assessment [~~fee~~] by the first day of

April for each year.

(6) [(7)] The annual assessment [fee] shall be received by the commission [~~department~~] no later than the first day of June for each year.

(7) [(8)] A licensee who fails to pay the [assessed] annual assessment fee shall be subject to denial, revocation, probation, or suspension of a license as prescribed in §139.32 of this title (relating to License Denial, Suspension, Probation, or Revocation).

§139.23. Application Procedures and Issuance of Licenses.

(a) (No change.)

(b) Definitions. The following terms when used in this section shall have the following meaning.

(1) Initial license--A license which is issued by the commission [~~department~~] to a [all] first-time applicant [~~applicants~~] for an abortion facility license, including an [those from] unlicensed abortion facility, to a [~~operating facilities and~~] licensed facility [~~facilities~~] for which a change of ownership is anticipated, and to a licensed facility for which a change of physical location will occur, that meets [~~meet~~] the requirements of the Act and this chapter and has [~~have~~] successfully completed the application procedures for an initial license as set out in subsection (c) of this section. Initial licenses shall expire in two years.

(2) Renewal license--A license issued by the commission [~~department~~] to a licensed abortion facility that meets all requirements of the Act and this chapter and has completed the application procedures for obtaining a renewal license as set out in subsection (d) of this section. Renewal licenses shall expire in two years.

(c) Application procedures for an initial license. This subsection establishes the application procedures for obtaining an initial license.

(1) Request for an application. Upon request for an abortion facility license, the commission [~~department~~] shall furnish a person with an application packet. Applications may also be obtained and submitted through the commission's [~~department's~~] web site.

(2) Application requirements. The applicant shall submit the information listed in subparagraph (C) of this paragraph to the commission [~~department~~].

(A) - (B) (No change.)

(C) The following documents shall be submitted with the original application form prescribed by the commission [~~department~~] and shall be originals or notarized copies:

(i) (No change.)

(ii) the name, mailing address, and street address of the abortion facility. The street address provided on the application shall be the physical location [~~address~~] from which the abortion facility will be operating and providing services;

(iii) - (v) (No change.)

(vi) if the applicant has held or holds an abortion facility license or has been or is an affiliate of another licensed facility, the relationship, including the name and current or last mailing address and physical location of the other facility, and the date such relationship commenced and, if applicable, the date it was terminated;

(vii) - (x) (No change.)

(xi) the following data concerning the applicant, the applicant's affiliates, and the managers of the applicant:

(I) - (II) (No change.)

(III) surrendering a license before expiration of the license or allowing a license to expire in lieu of the commission [~~department~~] proceeding with enforcement action;

(IV) - (VII) (No change.)

(xii) (No change.)

(3) Applicant copy. The applicant shall retain a copy of all documentation that is submitted to the commission [~~department~~].

(4) Application processing. Upon the commission's [~~department's~~] receipt of the application form, the required information described in paragraph (2)(C) of this subsection, and the initial license fee from an applicant, the commission [~~department~~] shall review the material to determine whether it is complete and correct.

(A) (No change.)

(B) If an abortion facility receives a notice from the commission [~~department~~] that some or all of the information required under paragraph (2)(C) of this subsection is deficient, the facility shall submit the required information no later than six months from the date of the notice.

(i) - (ii) (No change.)

(5) (No change.)

(6) Issuance of an initial license.

(A) - (B) (No change.)

(C) Pre-licensing Inspection [~~Pre-inspection conference~~]. Once the commission [~~department~~] has determined that the application form, the information required to accompany the application form, and the initial license fee are complete and correct, the commission [~~department~~] shall conduct an on-site pre-licensing inspection of the physical location [~~schedule a pre-inspection conference with the applicant in order to inform the applicant or his or her designee of the standards for the operation of the abortion facility. The department, at its discretion, may waive the pre-inspection conference. Upon recommendation by the pre-inspection conference, the department shall issue an initial license to the facility~~].

(D) [~~Pre-inspection recommendation.~~] After the on-site pre-licensing inspection [~~pre-inspection conference~~] has been completed [~~held~~], the commission [~~department~~] shall:

(i) issue an initial license to the owner of a facility, if the facility is found to be in compliance with the commission's [~~department's~~] requirements for initial licensure; or

(ii) deny the application, if the facility has not complied with the commission's [~~department's~~] requirements for issuing an initial license. The procedure for denial of a license shall be in accordance with §139.32 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(7) A commission [~~department~~] representative shall inspect the abortion facility in accordance with §139.31 of this title (relating to On-Site Inspections and Complaint Investigations of a Licensed Abortion Facility) within 60 days after the issuance of an initial license. If the commission [~~department~~] determines that a facility is not in compliance with the

provisions of the Act or this chapter after the initial on-site inspection, the commission [~~department~~] shall notify the facility. Notification shall be in accordance with §139.32 of this title.

(8) If for any reason, an applicant decides not to continue the application process, the applicant shall submit to the commission [~~department~~] a written request to withdraw its application. If an initial license has been issued, the applicant shall cease providing abortion services and return the initial license to the commission [~~department~~] with its written request to withdraw. The commission [~~department~~] shall acknowledge receipt of the request to withdraw. The license fee shall not be refunded.

(9) Continuing compliance by the licensed abortion facility with the provisions of the Act and this chapter is required [~~during the initial license period~~].

(d) Application procedures for renewal of a license.

(1) The commission [~~department~~] shall send notice of expiration of a license to the licensee at least 60 days before the expiration date of the license. If the licensee has not received notice of expiration from the commission [~~department~~] 45 days prior to the expiration date, it is the duty of the licensee to notify the commission [~~department~~] and request an application for a renewal license.

(2) The licensee shall submit the following items to the commission [~~department~~] by certified mail, marked confidential, and postmarked no later than 30 days prior to the expiration date of the license:

(A) - (C) (No change.)

(3) A facility shall not misstate a material fact on any documents required to be submitted to the commission [~~department~~] or required to be maintained by the facility in accordance with the provisions of the Act and this chapter.

(4) A commission [~~department~~] surveyor shall inspect a licensed abortion facility in accordance with §139.31(b) of this title.

(5) If a licensee makes timely and sufficient application for renewal, the license shall not expire until the commission [~~department~~] issues the renewal license or until the commission [~~department~~] denies renewal of the license.

(A) The commission [~~department~~] shall issue a renewal license to a licensee who meets the minimum standards for a license in accordance with the provisions of the Act and this chapter.

(B) The commission [~~department~~] may propose to deny the issuance of a renewal license if:

(i) based on the inspection report, the commission [~~department~~] determines that the abortion facility does not meet or is in violation of any of the provisions of the Act or this chapter;

(ii) - (iii) (No Change.)

(iv) a facility fails to file abortion reports [~~in accordance with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed)~~] or fails to ensure that a physician's [~~the physicians~~] report is filed in accordance with §139.5 of this title (relating to Additional Reporting Requirements [~~for Physicians~~]).

(6) If a licensee makes a timely application for renewal of a license, and action to revoke, suspend, place on probation, or deny renewal of the license is pending, the license does not expire but does extend until the application for renewal is granted or denied after the opportunity for a formal hearing. A renewal license shall not be issued unless the commission [~~department~~] has determined the reason for the proposed action no longer exists.

(7) If a suspension of a license overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in this subsection; however, the commission [~~department~~] may not renew the license until the commission [~~department~~] determines that the reason for suspension no longer exists.

(8) If the commission [~~department~~] revokes or does not renew a license, a person may apply for an initial license by complying with the requirements of the Act and this chapter at the time of reapplication. The commission [~~department~~] may refuse to issue a license, if the reason for revocation or non-renewal continues to exist.

(9) Upon revocation or non-renewal, a license holder shall return the original license to the commission [~~department~~].

(10) (No change.)

(e) Failure to timely renew a license.

(1) If a licensee fails to timely renew a license in accordance with subsection (d) of this section, the commission [~~department~~] shall notify the licensee that the facility shall cease operation on the expiration date of the license.

(2) (No change.)

(f) (No change.)

§139.24. Change of Ownership or Services, Change of Physical Location, and Closure of a Licensed Abortion Facility.

(a) The following provisions apply to change of ownership of the licensed abortion facility and affect the condition of a license.

(1) (No change.)

(2) The licensed abortion facility shall not materially alter any license issued by the commission [~~department~~].

(3) A person who desires to receive a license in its name for a facility licensed under the name of another person or to change the ownership of any facility shall submit an initial [~~a~~] license application and the initial license fee at least 60 calendar days prior to the desired date of the change of ownership. The application shall be in accordance with §139.23(c) of this title (relating to Application Procedures and Issuance of Licenses).

(4) (No change.)

(5) The commission [~~pre-inspection conference may, at the department's discretion, be waived for an applicant of a licensed abortion facility for a change in control of ownership. If the pre-inspection conference is waived, the department~~] shall conduct an on-site inspection prior to the issuance of [~~issue~~] an initial license to the new owner of the facility, in accordance with §139.23(c) of this title.

~~[(6) When a change of ownership has occurred, the department shall perform an on-site inspection of the facility within 60 days from the effective date of the change of ownership.]~~

(6) [~~(7)~~] The previous owner's license shall be void on the effective date of the change of ownership.

(7) [~~(8)~~] This subsection does not apply if a licensee is simply revising its

name as allowed by law (i.e., a corporation is amending the articles of incorporation to revise its name).

(8) [~~(9)~~] The sale of stock of a corporate licensee does not cause this subsection to apply.

(b) The following provisions apply to a change of physical location of the licensed abortion facility and affect the condition of a license.

(1) A facility that intends to move its operations to a different physical location shall notify the commission at least 60 days in advance of the relocation.

(2) A facility must apply for an initial license for the new physical location, submit the required initial license fee, and meet all requirements for an initial license in accordance with §139.23(c) of this title.

(c) [~~(b)~~] The following business changes affect the condition of a license and shall be reported to the commission [~~department~~].

(1) If a licensed abortion facility changes its business name, business mailing address, telephone number of the facility, administrator's telephone number, or fax number (if available), the administrator shall notify the commission [~~department~~] in writing within 15 calendar days after the effective date of the change.

(2) If a licensed abortion facility changes its administrator, the facility shall provide the name of the new administrator and effective date to the commission [~~department~~] in writing no later than 15 calendar days following such change.

(d) [~~(c)~~] The licensee shall notify the commission [~~department~~] at least 30 days in advance of a relocation.

(e) [~~(d)~~] The licensee shall notify the commission [~~department~~] in writing within 15 calendar days when a licensed abortion facility ceases operation. The licensee shall return the original license to the commission [~~department~~].

(f) [~~(e)~~] A licensed abortion facility shall have a written policy for the preservation and release of active and inactive medical records in the event the facility closes.

§139.25. Time Periods for Processing and Issuing a License.

(a) General.

(1) The date a license application is received is the date the application reaches Health Facility Licensing (commission) [~~the facility licensing group of the Department of State Health Services (department)~~].

(2) An application for an initial license is complete when the commission [~~department~~] has received, reviewed, and found acceptable the information described in §139.23(c)(2)(C) of this title (relating to Application Procedures and Issuance of Licenses).

(3) An application for a renewal license is complete when the commission [~~department~~] has received, reviewed, and found acceptable the information described in §139.23(d)(2) of this title.

(4) An application for a change of ownership or change of physical location license is complete when the requirements of [~~department has received, reviewed, and found acceptable the information described in~~] §139.24 of this title (relating to Change of Ownership or Services, Change of Physical Location, and Closure of a Licensed Abortion Facility) have been met.

(b) Time periods. An application from an abortion facility for an initial license, renewal license, change of physical location license, or change of ownership license shall be processed in accordance with the following time periods.

(1) The first time period begins on the date the commission [~~department~~] receives the application, and ends on the date the license is issued, or if the application is received incomplete, the period ends on the date the facility is issued a written notice that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete. The first time period is 45 days for initial, renewal, change of physical location, and change of ownership applications.

(2) (No change.)

(c) Reimbursement of fees.

(1) In the event the application is not processed in the time periods stated in subsection (b) of this section, the applicant has the right to request that the commission [~~department~~] reimburse in full the fee paid in that

particular application process. If the commission [~~department~~] does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request shall be denied.

(2) (No change.)

(d) Appeal. If the request for reimbursement as authorized by subsection (c) of this section is denied, the applicant may then appeal to the executive commissioner for a resolution of the dispute. The applicant shall give written notice to the executive commissioner requesting reimbursement of the fee paid because the application was not processed within the established time period. The commission [~~department~~] shall submit a written report of the facts related to the processing of the application and good cause for exceeding the established time periods. The executive commissioner shall make the final decision and provide written notification of the decision to the applicant and the commission [~~department~~].

§139.31. On-site Inspections and Complaint Investigations of a Licensed Abortion Facility.

(a) General. An on-site inspection shall determine if the requirements of the Act and this chapter are being met.

(1) An authorized representative of the commission [~~department~~] (surveyor) may enter the premises of a licensed abortion facility at reasonable times during business hours and at other times as it considers necessary to ensure compliance with:

(A) (No change.)

(B) an order of the executive commissioner;

(C) - (D) (No change.)

(2) The surveyor is entitled to access all books, records, or other documents maintained by or on behalf of the facility to the extent necessary to ensure compliance with the Act, this chapter, an order of the executive commissioner, a court order granting injunctive relief, or other enforcement action. The commission [~~department~~] shall maintain the confidentiality of facility records as applicable under federal or state law. Ensuring compliance includes permitting photocopying by a department surveyor or providing photocopies to a commission [~~department~~] surveyor of any records or other information by or on behalf of the commission [~~department~~] as necessary to determine or verify compliance with the Act or this chapter.

(3) By applying for or holding a license, the facility consents to entry and inspection of the facility by the commission [~~department~~] or representative of the commission [~~department~~] in accordance with the Act and this chapter.

(b) Inspection procedures.

(1) Except for purposes of an initial license application, all [AH] on-site inspections shall be unannounced and conducted[7] at least[7] annually. An on-site inspection for an initial license application, in accordance with §139.23(c) of this title (relating to Application Procedures and Issuance of Licenses), shall be scheduled with the applicant.

(2) The commission's [~~department's~~] surveyor shall hold a conference with the person who is in charge of a licensed abortion facility or a facility subject to an application prior to commencing the inspection for the purpose of explaining the nature and scope of the inspection. The surveyor shall hold an exit conference with the person who is in charge of the facility when the inspection is completed, and the surveyor shall identify any records that were duplicated. Any original facility records that are removed from a facility shall be removed only with the consent of the facility.

(3) The commission's [~~department's~~] authorized representative shall hold an exit conference and fully inform the person who is in charge of the facility of the preliminary finding(s) of the inspection, and shall give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings. The response shall be made a part of the inspection for all purposes, and shall be received by the commission [~~department~~] within 14 calendar days of receipt of the preliminary findings of the inspection by the facility.

(4) After the inspection is completed, the commission [~~department~~] shall provide the administrator of the facility specific and timely written notice of the findings of the inspection in accordance with paragraph (7) of this subsection.

(5) If the commission [~~department~~] determines that the facility is in compliance with minimum standards at the time of the on-site inspection, the commission [~~department~~] shall issue [~~send~~] a license to the facility, if applicable.

(6) If the surveyor finds there are deficiencies, the commission [~~department~~] shall provide the facility with a statement of the deficiencies; the surveyor's recommendation for further action; or if there are no deficiencies found, a statement indicating this fact.

(7) If the commission [~~department~~] representative finds there are deficiencies, the facility and the commission [~~department~~] shall comply with the following procedure.

(A) The commission [~~department~~] shall provide the facility with a statement of deficiencies on site at the time of the exit conference or within 14 calendar days of the exit conference.

(B) The facility administrator or person in charge shall sign the written statement of deficiencies and return it to the commission [~~department~~] with its plan of correction(s) for each deficiency within 14 calendar days of its

receipt of the statement of deficiencies. The signature does not indicate the person's agreement with deficiencies stated on the form.

(C) (No change.)

(i) An initial challenge to a deficiency(ies) shall be submitted in writing no later than 14 calendar days from the facility's receipt of the statement of deficiencies to the Manager, Health Care Quality, Health Facility Compliance Texas Health and Human Services Commission~~[Group, Department of State Health Services]~~, Post Office Box 149347, Austin, Texas 78714-9347. The initial written challenge shall include any and all documents supporting the facility's position.

(ii) If the initial challenge is favorable to the commission ~~[department]~~, the facility may request a review of the initial challenge by submitting a written request to the Director, Health Care Quality~~[Patient Quality Care Unit]~~, Texas Health and Human Services Commission ~~[Department of State Health Services]~~, Post Office Box 149347, Austin, Texas 78714-9347. The facility shall submit its written request for review of the initial challenge no later than 14 calendar days of its receipt of the commission's ~~[department's]~~ response to the initial challenge. The commission ~~[department]~~ shall not accept or review any documents that were not submitted with the initial challenge. A determination by the Director of Health Care Quality ~~[the Patient Quality Care Unit]~~, relating to a challenge to a deficiency(ies) shall be considered the final determination by the commission ~~[department]~~.

(iii) The commission ~~[department]~~ shall respond to any written challenge submitted under clauses (i) or (ii) of this subparagraph no later than 14 calendar days from its receipt.

(D) The commission ~~[department]~~ shall determine if the written plan of correction is acceptable. If the plan of correction(s) is not acceptable to the commission ~~[department]~~, the commission ~~[department]~~ shall notify the facility and request that the plan of correction be modified by telephone or resubmitted no later than 14 calendar days from receipt of such request by the facility.

(E) If the facility does not come into compliance by the required date of correction, the commission ~~[department]~~ may propose to deny, suspend, place on probation, or revoke the license in accordance with §139.32 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(F) Acceptance of a plan of correction by the commission ~~[department]~~

does not preclude the commission [~~department~~] from taking enforcement action as appropriate under §139.32 of this title.

(8) The commission [~~department~~] shall refer issues and complaints relating to the conduct or action(s) by licensed health care professionals to their appropriate licensing boards.

(c) Complaints.

(1) In accordance with §139.50 of this title (relating to Disclosure Requirements), all licensed abortion facilities are required to provide the woman on whom the abortion is to be performed and her guardian, if present, if the patient is a minor at time of the initial visit or if guardianship is required, with a written statement that complaints relating to the abortion facility may be registered with the Manager, Health Care Quality, Health Facility Compliance [Group], Texas Health and Human Services Commission [~~Department of State Health Services~~], Post Office Box 149347, Austin, Texas 78714-9347, (888) 973-0022.

(2) The commission [~~department~~] shall evaluate all complaints against licensed abortion facilities. All complaints submitted to the commission [~~department~~] shall be in writing and signed by the complainant. Only those allegations determined to be relevant to the Act or this chapter shall be authorized for investigation. All information pertaining to a complaint is strictly confidential.

(3) The commission [~~department~~] or its authorized representative may enter the premises of an abortion facility during normal business hours as necessary to assure compliance with the Act and this chapter. The investigation may be conducted on site, by phone or by mail.

(4) Conduct of the on-site investigation of a licensed abortion facility shall include, but not be limited to:

(A) a conference prior to commencing the on-site investigation for the purpose of explaining the nature and scope of the investigation between the commission's [~~department's~~] authorized representative and the administrator of the abortion facility, or his or her designee;

(B) - (D) (No change.)

(E) a conference at the conclusion of the inspection between the commission's [~~department's~~] representative and the administrator, or his or her designee of the facility; and

(F) identification by the commission's [~~department's~~] representative of any facility documents that have been reproduced.

(5) If the commission [~~department~~] finds that there are deficiencies following the on-site inspection, the provisions of subsection (b)(6) and (7) of this section shall apply.

(6) The commission [~~department~~] shall review the report of the investigation and determine the validity of the complaint.