

**Department of State Health Services
Council Agenda Memo for State Health Services Council
June 14, 2012**

Agenda Item Title: Amendments to rules concerning the regulation of abortion facilities

Agenda Number: 4.e

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Health Facility Program is within the Regulatory Licensing Unit, Health Care Quality Section, of the Regulatory Services Division. The Health Facility Program monitors health care delivery provided by regulated health care facilities to ensure high quality care to the people of Texas. The Program issues licenses to abortion facilities, ambulatory surgical centers, general and special hospitals and conducts inspections to determine compliance with the rules. Findings of non-compliance may result in referral for escalated enforcement action.

There are 39 licensed abortion facilities. The budget and source of funding is General Revenue and program costs are offset by licensing fees.

Summary:

The purpose of the amendments is to comply with Texas Health and Safety Code (HSC), Chapter 245, which requires abortion facilities be licensed by the Department of State Health Services (DSHS). HSC, Section 245.011 mandates annual reporting to DSHS on each abortion that is performed in an abortion facility. DSHS rules in 25 Texas Administrative Code, Chapter 139, concerning Abortion Facility Reporting and Licensing, implement HSC, Chapter 245. Existing annual reporting requirements apply to any place where abortions are performed, which includes licensed, unlicensed and exempt facilities.

The proposed amendments to Chapter 139 update existing reporting requirements for all abortions performed. Additional information and data will be available to aid in DSHS's regulatory functions and capabilities, thereby benefiting healthcare facilities, practitioners, consumers and their family members. Aggregate data collected will be used by DSHS in order to assess the quality and efficiency of health care.

The proposed rule changes specifically:

- provide language to specify the required data for the annual reporting of all abortions performed; and
- amend reporting requirements for physicians by adding a complications reporting form submission to current requirements.

The effectiveness of each amendment is tested by conducting onsite initial surveys, resurveys, complaint investigations, and follow-up visits to verify corrective action has been completed for all rule violations that have been identified. Resurveys are conducted annually. Performance measures include the number of facility surveys conducted, the number of complaint investigations conducted, and the percentage of health facilities found to be in compliance with each rule.

These measurements assist DSHS in determining the effectiveness of the rules and resulting facility compliance. Harm and risk of harm, and associated negative outcomes, related to these amendments are reported to DSHS via complaints, facility self-reporting and incident reports. Additionally, incidental findings of this nature are discovered via routine surveys and inspections. Substantiated negative outcomes are evaluated and reported for Enforcement Unit review and may result in subsequent enforcement action.

Minimal costs are expected to be incurred as a result of the proposed amendments, as reporting requirements already exist.

Key Health Measures:

The proposed rule changes will provide DSHS with additional data to carry out its regulatory functions and conduct demographic and trend analysis. If reported numbers reveal a reason for concern, such as a particularly high rate of complications at a certain facility, DSHS may investigate further from a regulatory perspective to ensure patient safety.

The required reporting of abortion complications and amending annual reporting requirements will provide measurable data over time to assess the number of abortion-related complications, the number of women requiring additional medical care due to complications, and other statistical information impacting healthy outcomes for women.

Summary of Input from Stakeholder Groups:

Stakeholders include hospitals, abortion facilities, ambulatory surgical centers, physicians, professional organizations, facility clients, facility staff and various advocacy groups. Stakeholders were notified via e-mail and posting on the Department of State Health Services website. An external stakeholder meeting was held on April 5, 2012.

Comments and inquiries have been received from numerous providers, stakeholders, legislative offices and the media regarding the proposed rule changes. Generally, most inquiries are related to the purpose of the new requirements, which include comments that the changes are not statutorily mandated, that some of the physician reporting requirements regarding abortion complications is duplicative of existing reporting requirements, and that DSHS should define what is considered a complication of an abortion.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #4.e.

Approved by Assistant Commissioner/Director: Kathryn C. Perkins, R.N., M.B.A **Date:** 5/9/2012

Presenter: Kathryn C. Perkins, R.N., M.B.A. **Program:** Regulatory Services **Phone No.:** 512-834-6660

Approved by CCEA: Carolyn Bivens **Date:** 5/9/12

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 139. Abortion Facility Licensing
Subchapter A. General Provisions
Amendments §139.4 and §139.5

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §139.4 and §139.5, concerning the regulation of abortion facilities.

BACKGROUND AND PURPOSE

Health and Safety Code, Chapter 245, requires certain abortion facilities to be licensed by the department. Section 245.011 mandates annual reporting to the department on each abortion that is performed in an abortion facility, which is defined by statute as any place where an abortion is performed. Chapter 139 of this title, Abortion Facility Reporting and Licensing rules, implements Health and Safety Code, Chapter 245. Existing annual reporting requirements apply to all licensed abortion facilities and all facilities where abortions are performed.

SECTION-BY-SECTION SUMMARY

The amendment to §139.4(a) - (e) provides revised and new language to specify the required data to be reported annually to the department by abortion facilities. Subsections (d) - (f) were renumbered as (f) - (h) without changes to the rule text.

Section 139.5(3) amends reporting requirements for physicians. Additionally, the amendment revises reporting requirements concerning abortion complications by adding a "complications reporting form" submission to existing physician reporting requirements.

FISCAL NOTE

Renee Clack, Section Director, Health Care Quality Section, has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Clack has also determined that there will not be an adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed because this was determined by interpretation of the rules that small business and micro-businesses will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There will be no significant economic costs to persons who are required to comply with the sections as proposed. There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Clack has also 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 rules protect the health, safety, and welfare of patients receiving services in abortion facilities, personnel, and the public.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by 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

The department 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 Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Ellen Cooper, Manager, Facility Licensing Group, Regulatory Licensing Unit, Division of Regulatory Services, Department of State Health Services, P.O. Box 149347, Mail Code 2835, Austin, Texas 78714-9347, (512) 834-6639 or by email to ellen.cooper@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized by Health and Safety Code, §245.011, concerning rules and minimum standards for the licensing and regulation of abortion facilities required to obtain a

license under this chapter; and Government Code, §531.0055 and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendments affect Health and Safety Code, Chapters 245 and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

Subchapter A. General Provisions.

§139.4. Annual Reporting Requirements for All Abortions Performed.

(a) The purpose of this section is to implement the annual abortion reporting requirements for each location where abortions are performed, which includes licensed, unlicensed, and exempt facilities, including physicians offices. **[of the Texas Abortion Facility Reporting and Licensing Act (Act), Health and Safety Code, §245.011, which mandates that each abortion facility shall submit an annual report to the Department of State Health Services on each abortion performed at the abortion facility. This section applies to any place where abortions are performed, and therefore applies to licensed, unlicensed, and exempt facilities (including physicians).]**

(b) The report may not identify by any means the physician performing the abortion or the patient. **[Abortion facilities shall submit an abortion report on each abortion that was performed at the facility on at least an annual basis. The facility may choose to submit the abortion reports on a monthly or quarterly basis for greater efficiency.]**

(c) The report must include: **[The reporting period for each abortion facility is January 1 - December 31 of each year. Each facility shall submit the abortion report(s) to the department no later than January 31 of the subsequent year.]**

(1) whether the abortion facility at which the abortion is performed is licensed under this chapter;

(2) the patient's year of birth, race, marital status, and state and county of residence;

(3) the type of abortion procedure;

(4) the date the abortion was performed;

(5) whether the patient survived the abortion, and if the patient did not survive, the cause of death;

(6) the period of gestation based on the best medical judgment of the attending physician at the time of the procedure;

(7) the date, if known, of the patient's last menstrual cycle;

(8) the number of previous live births of the patient;

(9) the number of previous induced abortions of the patient;

(10) the patient's highest level of education;

(11) whether the patient viewed the printed material provided under Health and Safety Code, Chapter 171;

(12) whether the sonogram image, verbal explanation of the image, and the audio of the heart sounds were made available to the patient;

(13) whether the patient completed the "Abortion and Sonogram" election form;

(14) method used to dispose of fetal tissue and remains;

(15) if patient is younger than 18, how consent was obtained; and

(16) the method of pregnancy verification.

(d) Except as provided by Health and Safety Code, §245.023, all information and records held by the department under this chapter are confidential and are not open records for the purposes of, Government Code, Chapter 552. That information may not be released or made public on subpoena, or otherwise, except that release may be made:

(1) for statistical purposes, but only if a person, patient, or abortion facility is not identified;

(2) with the consent of each person, patient, and abortion facility identified in the information released;

(3) to medical personnel, appropriate state agencies, or county and district courts to enforce this chapter; or

(4) to appropriate state licensing boards to enforce state licensing laws.

(e) The reporting period for each abortion facility is January 1 - December 31 of each year. Each facility shall submit the abortion report(s) to the department no later than January 31 of the subsequent year.

(f) [(d)] The abortion reports shall be submitted:

(1) on forms approved by the department, by certified mail marked as confidential, to the Department of State Health Services, Vital Statistics Unit, Post Office Box 4124, Austin, Texas 78765-4124;

(2) on a floppy disk in a format approved by the department, by certified mail marked as confidential, to the Department of State Health Services, Vital Statistics Unit, Post Office Box 4124, Texas 78765-4124; or

(3) via a modem in a format approved by the department.

(g) ~~[(e)]~~ The first annual reporting period for a licensed abortion facility commences on the day the initial license is issued. The report(s) shall contain data for the calendar year in which the initial license is issued. If the abortion facility's licensure status changes, the report(s) shall contain data from the date the initial license was issued through the date the initial license expired, was revoked, was suspended, or was withdrawn.

(h) ~~[(f)]~~ If a change of ownership has occurred, the previous owner shall submit the report(s) commencing from the date of the previous reporting period and ending on the date the change in ownership of the facility occurred; the report(s) is due 30 days after the date of acquisition. The annual reporting period for the newly acquired facility commences on the day the initial license is issued and shall contain data for the calendar year in which the initial license is issued. If the newly acquired facility's licensure status changes, the report(s) shall contain data from the date the initial license was issued through the date the initial license expired, was revoked, was suspended, or was withdrawn.

§139.5. Additional Reporting Requirements for Physicians.

In addition to the annual reporting required by §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed), physicians shall comply with this section when performing third trimester abortions and [or] when performing emergency abortions on certain minors or when abortion complications occur.

(1) - (2) (No change.)

(3) Reporting requirements for abortion complications.

(A) Within 30 calendar days after the date the complication is discovered, a physician shall submit an abortion complication report on a form provided by the department; and via certified mail marked as confidential to the Department of State Health Services, Vital Statistics Unit, Post Office Box 4124, Austin, Texas 78765-4124; or electronically, confidentially via an encrypted format approved by the department.

(B) The report must include:

(i) the date of the abortion that caused or may have caused the complication;

(ii) the type of abortion that caused or may have caused the complication;

performed; (iii) the name and type of facility where the abortion was

diagnosed and treated; (iv) the name, date and type of facility where the complication was

(v) description of complications;

performed; and (vi) the number of weeks of gestation at which the abortion was

(vii) the number of previous live births of the patient.