

**Department of State Health Services
Council Agenda Memo for State Health Services Council
February 23, 2012**

Agenda Item Title: New rules concerning a vaccine preventable disease policy for health care facilities regulated and operated by DSHS

Agenda Number: 4.b

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 and conducts inspections to determine compliance with the rules. Findings of non-compliance may result in referral for escalated enforcement action.

The budget and source of funding is General Revenue and program costs are offset by licensing fees.

Senate Bill (SB) 7, Article 8, 82nd Legislature, First Called Session, 2011, requires certain health care facilities licensed by the Department of State Health Services (DSHS) and state hospitals maintained or operated by DSHS, to develop and implement a vaccine preventable disease policy for their employees and other individuals who are routinely and directly exposed to patients.

Summary:

The purpose of the new rules is to mandate that a health care facility develop, implement, and enforce a policy to protect patients from the vaccine preventable diseases that are included in the most current recommendations of the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices. The new rules will implement SB 7 and apply to seven regulatory programs administered by DSHS, as well as the state hospitals maintained or operated by DSHS. The DSHS programs affected have unique rule sets; therefore, the most efficient way to implement the bill is to amend the broad-scope 25 TAC, Chapter 1, rather than amending individual chapters in 25 TAC. The new requirements are identical for the seven programs that include Hospitals; Ambulatory Surgical Centers; Birthing Centers; Abortion Facilities; Special Care Facilities; End Stage Renal Disease Facilities; and Freestanding Emergency Medical Care Facilities; as well as state hospitals.

The policy must:

- require covered individuals to receive vaccines based on the level of risk the individual presents to patients by their routine and direct exposure to patients;
- include procedures for a covered individual to claim an exemption from the required vaccines for medical conditions the CDC identifies as contraindications or precautions;
- include procedures an exempt individual must follow to protect facility patients from exposure to disease;
- require the health care facility to maintain a written or electronic record of each covered individual's compliance with or exemption from the policy; and
- include disciplinary actions the health care facility is authorized to take against a covered individual who fails to comply with the policy.

The policy may include procedures for a covered individual to claim an exemption from the required vaccine policy based on reasons of conscience, including a religious belief. New rules permit the facility to prohibit an exempt individual from having contact with facility patients during a public disaster, and provide that DSHS may take enforcement action against facilities that violate these rules.

A facility is not required to have a policy on vaccine preventable diseases in effect until September 1, 2012.

Key Health Measures:

The new rules will help protect patients from vaccine preventable diseases in health care facilities regulated and operated by DSHS. There are no anticipated costs to facilities associated with implementing this law as most health care facilities already have vaccine policies in place and there is no mandate in the law that requires facilities to absorb the costs of vaccinating employees.

Summary of Input from Stakeholder Groups:

The draft rules have been posted to the DSHS Regulatory Health Facilities Licensing website under *Hot Topics and Draft and Proposed Rules*; and were shared at the Hospital Facility Stakeholder meeting in October 2011. To date, only one comment has been received regarding how the facility should document that student volunteers have received vaccinations.

Proposed Motion:

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

Approved by Assistant Commissioner/Director: Kathryn C. Perkins, R.N.,M.B.A. **Date:** 1/20/2012

Presenter: Ellen Cooper, Health Facilities Group Manager **Program:** Regulatory Licensing Unit **Phone No.:** (512) 834-6639

Approved by CCEA: Carolyn Bivens **Date:** 1/20/2012

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 1. Miscellaneous Provisions
Subchapter Z. Vaccine Preventable Disease Policy.
New §§1.701-1.704

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes new §§1.701 - 1.704, concerning a Vaccine Preventable Disease Policy for health care facilities regulated and operated by the department.

BACKGROUND AND PURPOSE

This new subchapter will implement Senate Bill (SB) 7, Article 8, 82nd Legislature, First Called Session, 2011, which added new Health and Safety Code, Chapter 224, (regarding Policy on Vaccine Preventable Diseases). By their terms, these provisions require state hospitals and certain health care facilities licensed by the department, to develop, implement, and enforce a Vaccine Preventable Disease Policy applicable to their employees and other individuals who are routinely and directly exposed to patients.

These new rules apply to seven regulatory programs administered by the department, as well as to hospitals the state maintains or operates. Programs of the department affected by the new law have unique rule sets, and are codified in seven different chapters. Therefore, the most efficient way to implement SB 7 is to amend 25 TAC, Chapter 1, the broad-scope rule set of the department which applies across programs and to state hospital operations as well, rather than amending seven individual rule sets. The new requirements are identical for the programs and state hospitals affected. Specifically, the programs affected are: Hospitals, Health and Safety Code, Chapter 241; Ambulatory Surgical Centers, Health and Safety Code, Chapter 243; Birthing Centers, Health and Safety Code, Chapter 244; Abortion Facilities, Health and Safety Code, Chapter 245; Special Care Facilities, Health and Safety Code, Chapter 248; End Stage Renal Disease Facilities, Health and Safety Code, Chapter 251; and Freestanding Emergency Medical Care Facilities, Health and Safety Code, Chapter 254; as well as state hospitals.

SECTION-BY-SECTION SUMMARY

New §§1.701 - 1.704 require that each health care facility develop, implement, and enforce a policy to protect patients from the vaccine preventable diseases that are included in the most current recommendations of the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention (CDC).

The policy must require covered individuals to receive vaccines based on the level of risk the individuals present to patients by their routine and direct exposure to patients; include procedures for covered individuals to claim an exemption from the required vaccines for medical conditions the CDC identifies as contraindications or precautions; include procedures exempt individuals

must follow to protect facility patients from exposure to disease; require the health care facility to maintain written or electronic records of covered individuals' compliance with or exemption from the policy; and include disciplinary actions the health care facility is authorized to take against covered individuals who fail to comply with the policy.

The new rules also include provisions for covered individuals to claim an exemption from the required vaccine policy based on reasons of conscience, including a religious belief; for prohibiting exempt individuals from having contact with facility patients during a public disaster; and for taking enforcement action, including assessing administrative penalties against facilities that violate these rules.

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 not be 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 are no anticipated costs to facilities associated with implementing this law as most health care facilities already have vaccine policies in place and there is no mandate in the law that requires facilities to absorb the costs of vaccinating employees or other covered individuals. Any economic costs to persons who are required to comply with the sections as proposed will be determined by whether the health facility itself decides to bear the cost of the required vaccinations or requires covered individuals to pay for them, as well as staff training and reporting costs, all of which are expected to be minimal. There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Clack also 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 rules help protect patients and those rendering care at health care facilities from vaccine preventable diseases.

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 new sections are authorized by Health and Safety Code, §241.026; §243.010; §244.010; §245.010; §248.026; §251.014; §254.151; and Government Code, §531.0055 and by 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 new sections affect Health and Safety Code, Chapters 241, 243 - 245, 248, 251, 254 and 1001; and Government Code, Chapter 531.

Legend: (Proposed New Rules)
Regular Print = Proposed New Language

Subchapter Z. Vaccine Preventable Disease Policy.

§1.701. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Covered individual--

- (A) an employee of the health care facility;
- (B) an individual providing direct patient care under a contract with a health care facility; or
- (C) an individual to whom a health care facility has granted privileges to provide direct patient care.

(2) Department--Department of State Health Services.

(3) Health care facility--

- (A) a hospital licensed under the Health and Safety Code, Chapter 241;
- (B) an ambulatory surgical center licensed under the Health and Safety Code, Chapter 243;
- (C) a birthing center licensed under the Health and Safety Code, Chapter 244;
- (D) an abortion facility licensed under the Health and Safety Code, Chapter 245;
- (E) a special care facility licensed under the Health and Safety Code, Chapter 248;
- (F) an end stage renal disease facility licensed under the Health and Safety Code, Chapter 251;
- (G) a freestanding emergency medical care facility licensed under the Health and Safety Code, Chapter 254; or
- (H) a hospital maintained or operated by this state.

(4) Regulatory authority--Department of State Health Services.

(5) Vaccine preventable diseases--Diseases included in the most current recommendations of the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention.

§1.702. Vaccine Preventable Diseases Policy.

(a) Each health care facility shall develop, implement, and enforce a policy and procedures to protect its patients from vaccine preventable diseases.

(b) The policy must:

(1) require covered individuals to receive vaccines for the vaccine preventable diseases specified by the facility based on the level of risk the individual presents to patients by the individual's routine and direct exposure to patients;

(2) specify the vaccines a covered individual is required to receive based on the level of risk the individual presents to patients by the individual's routine and direct exposure to patients;

(3) include procedures for verifying whether a covered individual has complied with the policy;

(4) include procedures for a covered individual to be exempt from the required vaccines for the medical conditions identified as contraindications or precautions by the federal Centers for Disease Control and Prevention;

(5) for a covered individual who is exempt from the required vaccines, include procedures the individual must follow to protect facility patients from exposure to disease, such as the use of protective medical equipment, such as gloves and masks, based on the level of risk the individual presents to patients by the individual's routine and direct exposure to patients;

(6) prohibit discrimination or retaliatory action against a covered individual who is exempt from the required vaccines for the medical conditions identified as contraindications or precautions by the federal Centers for Disease Control and Prevention, except that required use of protective medical equipment, such as gloves and masks, may not be considered retaliatory action for purposes of this section;

(7) require the health care facility to maintain a written or electronic record of each covered individual's compliance with or exemption from the policy; and

(8) include disciplinary actions the health care facility is authorized to take against a covered individual who fails to comply with the policy.

(c) The policy may include procedures for a covered individual to be exempt from the required vaccines based on reasons of conscience, including a religious belief.

§1.703. Disaster Exemption.

(a) In this section, "public health disaster" has the meaning assigned by the Health and Safety Code, §81.003.

(b) During a public health disaster, a health care facility may prohibit a covered individual who is exempt from the vaccines required in the policy developed by the facility under §1.702 of this title (relating to Vaccine Preventable Diseases Policy), from having contact with facility patients.

§1.704. Disciplinary Action.

A health care facility that violates this subchapter is subject to enforcement action by the department, including but not limited to imposition of administrative penalties, in the same manner, to the same extent, and pursuant to the same procedures, as if the health care facility had violated a provision of the applicable chapter of the Health and Safety Code or department rules as follows:

- (1) for hospitals, Health and Safety Code, Chapter 241, and 25 TAC Chapter 133;
- (2) for ambulatory surgical centers, Health and Safety Code, Chapter 243, and 25 TAC Chapter 135;
- (3) for birthing centers, Health and Safety Code, Chapter 244, and 25 TAC Chapter 137;
- (4) for abortion facilities, Health and Safety Code, Chapter 245, and 25 TAC Chapter 139;
- (5) for special care facilities, Health and Safety Code, Chapter 248, and 25 TAC Chapter 125;
- (6) for end stage renal disease facilities, Health and Safety Code, Chapter 251, and 25 TAC Chapter 117; and
- (7) for freestanding emergency medical care facilities, Health and Safety Code, Chapter 254, and 25 TAC Chapter 131.