

**Department of State Health Services
Agenda Item for State Health Services Council
November 17, 2005**

Agenda Item Title: Repeal of 25 TAC Section 96.601; Amend 25 TAC Sections 96.101, 96.201 - 96.203, 96.301 - 96.304, 96.401 - 96.402, 96.501, Relating to Bloodborne Pathogen Control

Agenda Number: 3d

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Infectious Disease Surveillance and Epidemiology Branch is responsible for assisting local or regional public health officials in investigating outbreaks of acute infectious disease or any report of isolated cases of rare or unusual disease, such as plague, cholera, or botulism.

Summary: The rules concern the establishment of an exposure control plan designed to minimize exposure of state government employees to bloodborne pathogens and implements a registration program for needleless systems and sharps with engineered sharp injury protections. The rules are up for the four (4) year rule review.

The amendments provide clarification to definitions; update legacy agency names and titles; provide a new website for information on bloodborne pathogen control; add a 2-year period for registration and renewal fees; change the date of expiration of a waiver from a stipulated date of December 31, 2001, to December 31 annually; revise the authorization of the 1990 federal census to the 2000 federal census as the reference in determining county populations; and change the waiver request date from January 1, 2001, to January 1 annually. The repeal of Section 96.601 is necessary because the reference to the effective date of the rules is no longer accurate.

Summary of Stakeholder Input to Date (including advisory committees):

There is not an advisory committee associated with bloodborne pathogen control.

State government employees with potential exposure to blood and other infectious body fluids are the primary stakeholders. Proposed amendments to the Department's and organization unit names as well as changes in title names of the Department's commissioners do not necessitate stakeholder input. Device registration fee payment changes required by HB 2292 were previously implemented and thus do not necessitate stakeholder input.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item # 3d.

Agenda Item Approved by: Debra Stabeno

Presented by: Thomas Betz, MD **Title:** Branch Manager

Program/Division: Infectious Disease Surveillance and Epidemiology Branch

Contact Name/Phone: Kathryn Gardner/458-7676

Date Submitted

10/24/2005

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 96. Bloodborne Pathogen Control

Amendments §§96.101, 96.201 - 96.203, 96.301 - 96.304, 96.401 - 96.402, 96.501

Repeal §96.601

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 §§96.101, 96.201 - 96.203, 96.301 - 96.304, 96.401 - 96.402, 96.501 and the repeal of 96.601 concerning the applicability, minimum standards, safety recommendations, device registration procedures and fees, and sharps injury logs of bloodborne pathogen exposure control plans.

BACKGROUND AND PURPOSE

The repeal and amendments are necessary to comply with Health and Safety Code, §§81.301 – 81.307, which requires the department to establish an exposure control plan designed to minimize exposure of employees to bloodborne pathogens and to implement a registration program for needleless systems and sharps with engineered sharp injury protections; H.B. 2292, 78th Legislature, Regular Session, 2003, §2.42, added Health and Safety Code, §12.0112, which requires that the term for licenses issued or renewed after January 1, 2005, will be two years.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 96.101, 96.201 - 96.203, 96.301 - 96.304, 96.401 - 96.402, 96.501, and 96.601 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed and required by law; except that §96.601 will be repealed because the rule is no longer necessary.

SECTION-BY-SECTION SUMMARY

Amendments to §96.101 add more components to the definitions of "Governmental unit" and also provide additional information concerning the contracting of the Hepatitis B, C, and Human immunodeficiency viruses; §§96.201 - 96.203, 96.301 - 96.304, 96.401, 96.402, and 96.501 update and correct the department's reference from the "Texas Department of Health" to the "Department of State Health Services"; §§96.202, 96.303, and 96.401 provide a new website for information on bloodborne pathogen control; amendments to §§96.301 and 96.501 reflect changes in the Department of State Health Services' organizational unit names and commissioner titles; amendments to §§96.302 and 96.304 add a 2-year period for registration and renewal fees; §96.501 is amended to change the date of expiration of a waiver from a stipulated date of December 31, 2001, to December 31 annually; to revise the authorization of the 1990 federal census and identify the 2000 federal census as the reference in determining county populations; and to change the request for a waiver date from January 1, 2001, to January 1 annually.

Section 96.601 is being repealed because the reference to the effective date of the rules is no longer relevant.

FISCAL NOTE

Jon Huss, Section Director, Community Preparedness Section, has determined that for the first year of the first five years that the sections are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed. The effect on state government will be an increase in revenue for the first year of \$2,000 due to the two-year device registration fee. For years two through five, there will be no fiscal impact and no change in revenue. There will be no effect on local government.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Huss has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Mr. Huss 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 public benefit anticipated as a result of administering the sections is reducing incidence to sharps injuries and the prevention of communicable disease in government employees and their contacts.

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 the 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 proposed rules do 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, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Kathryn Gardner, DrPH, RNC, Infectious Disease Surveillance and Epidemiology Branch, Infectious Disease Control Unit, Department of

State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512/458-7676 or by e-mail to Kathryn.Gardner@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 Deputy General Counsel, Linda Wiegman, 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 proposed repeal and amendments are authorized by Health and Safety Code, Subchapter H, Bloodborne Pathogen Exposure Control Plan, §§81.301 – 81.307. Specifically §§81.303 – 81.304 requires the department by rule to establish and implement an exposure control plan designed to minimize exposure of employees to bloodborne pathogens; §81.305 which requires the department to recommend that governmental units implement needleless systems and sharps with engineered sharps injury protection for employees; §81.306 which requires that the department by rule require that information concerning exposure incidents be recorded in a log; and §81.307 which requires that the department by rule implement a registration program for existing needleless systems and sharps with engineered sharp injury protections; Health and Safety Code, §12.0112, which requires that the term for licenses issued or renewed after January 1, 2005, will be two years; 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 Chapter 1001, Health and Safety Code.

The proposed repeal and amendments affect the Health and Safety Code, Chapters 81 and 1001; and Government Code, Chapter 531. Review of the rules implements Government Code §2001.039.

Legend: (Proposed Amendments)

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

§96.101. Definitions.

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

(1) – (10) (No change.)

(11) Governmental unit – This state and any agency of the state, including a division, section, unit, branch, department, bureau, board, commission, or office and includes:

(A) – (B) (No change.)

(12) HBV – Hepatitis B virus. A virus that may be contracted through exposure to blood and/or body fluids and can result in chronic liver infections and cirrhosis.

(13) HCV – Hepatitis C virus. A virus that may be contracted through exposure to blood and/or body fluids and may result in chronic liver disease.

(14) (No change.)

(15) HIV – Human immunodeficiency virus. The HIV virus may be contracted through blood and/or body fluids and can result in Acquired Immune Deficiency Syndrome (AIDS), a condition in which the body is unable to fight infections.

(16) – (23) (No change.)

§96.201. Applicability.

(a) (No change.)

(b) These governmental units would include, but not limited to, hospital district hospitals, city hospitals, county hospitals, city/county hospitals, hospital authority hospitals, local health departments, Department of State Health Services regions and hospitals, other state hospitals and state schools [**regional health departments, state hospitals, Mental Health Mental Retardation state hospitals and state schools**], community mental health mental retardation centers, Texas Youth Commission, Texas Department of Criminal Justice, local- or state-funded university student infirmaries, public school district clinics, emergency medical services, local- or state-funded long term care facilities, and blood banks.

(c) (No change.)

§§96.202, 96.203, 96.301

§96.202. Exposure Control Plan.

(a) The exposure control plan (plan) developed by the Department of State Health Services [**Texas Department of Health**] (department), is adopted as the minimum standard to implement Health and Safety Code, §81.304. The plan is designed to minimize exposure of employees as described in §96.201 of this title (relating to Applicability) and includes policies relating to occupational exposure to bloodborne pathogens, training and educational requirements for employees, measures to increase vaccination of employees, and increased use of personnel protective equipment by employees.

(b) Copies of the plan are available on the Internet at http://www.dshs.state.tx.us/idcu/health/bloodborne_pathogens/reporting/ [<http://www.tdh.state.tx.us/ideas/report/sharps.htm>] or from the Department of State Health Services regional offices [**Texas Department of Health Public Health Regional offices.**]

§96.203. Minimum Standards.

(a) This exposure control plan (plan) is provided by the Department of State Health Services [**Texas Department of Health**] (department) to be analogous with Title 29 Code of Federal Regulation §1910.1030, Occupational Safety and Health Administration (OSHA), Bloodborne Pathogens Standard as specified in Health and Safety Code, §81.304.

(b) – (c) (No change.)

§96.301. Safety Recommendations.

(a) The Department of State Health Services [**The Texas Department of Health**] (department) recommends that governmental units implement needleless systems and sharps with engineered sharps injury protection for employees.

(b) Waiver for undue burden.

(1) (No change.)

(2) A report of the evaluation committee's decision to request a waiver shall be submitted in writing prior to January 1st of each year to the Assistant Commissioner, Prevention and Preparedness, [Associate Commissioner, Disease Control and Prevention,] 1100 West 49th Street, Suite G-401, Austin, Texas 78756.

(3) (No change.)

(4) The use of a prefilled syringe that is approved by the federal Food and Drug Administration may not be prohibited. [**This prohibition expires on May 1, 2003.**]

§§96.301 - 96.303

(c) Evaluation committee

(1) (No change.)

(2) Whenever possible, the governmental entity establishing the evaluation committee shall consider using committees with similar duties already in existence [**on September 1, 1999.**]

§96.302. Device Registration.

(a) The Department of State Health Services [**The Texas Department of Health**] (department) shall compile and maintain a list of needleless system devices and sharps devices with engineered sharps injury protection that are available in the commercial marketplace and registered with the department to assist governmental units to comply with this chapter.

(b) – (i) (No change.)

(j) All device registration certificates shall expire two years from the date of issuance [**on December 31, 2001 and annually thereafter**].

(k) Renewal of registration.

(1) (No change.)

(2) The renewal registration certificate shall be valid for two years [**through December 31 of the year issued**].

(3) – (4) (No change.)

(l) (No change.)

§96.303. Registration Procedures.

(a) Any device manufacturer desiring to register a needleless system device or sharps device with engineered sharps injury protection shall make written application for registration on forms provided by the Department of State Health Services [**Texas Department of Health**] (department). A separate completed application is required for each device to be registered. Registration application forms may be obtained from the Department of State Health Services [**Texas Department of Health, Bureau of Food and Drug Safety**], 1100 West 49th Street, Austin, Texas, 78756.

(b) (No change.)

§§96.304, 96.401, 96.402

§96.304. Registration Fees.

The Department of State Health Services [**Texas Department of Health**] (department) shall charge a fee to register a needleless system device or sharps device with engineered sharps injury protection.

(1) An initial registration fee of \$2,500 [**\$1,500**] shall be required for each device registered for a two-year period.

(2) A renewal fee of \$2,000 [**An annual renewal fee of \$1,000**] shall be required for renewing the registration of each device for a two-year term.

(3) (No change.)

§96.401. Sharps Injury Log.

(a) – (d) (No change.)

(e) A chief administrative officer for each facility within a governmental unit or the designee shall report the contaminated sharps injury to the local health authority where the facility is located. The local health authority, acting as an agent for the Department of State Health Services [**Texas Department of Health**] (department), shall receive and review the report for completeness, and submit the report to the department. If no local health authority is appointed for the jurisdiction where the facility is located, the report shall be made to the regional director of the Department of State Health Services [**Texas Department of Health**] (department) regional office in which the facility is located.

(f) A contaminated sharps injury shall be reported on the department's Contaminated Sharps Injury Reporting Form or through an electronic means established by the department. Copies of the Contaminated Sharps Injury Reporting Form can be obtained on the Internet at http://www.tdh.state.tx.us/ideas/bloodborne_pathogens/reporting/ [<http://www.tdh.state.tx.us/ideas/report/sharps.htm>] or from the Department of State Health Services regional [**Texas Department of Health Public Health Regional**] offices.

§96.402. Confidentiality Statement.

(a) All information and materials obtained or compiled by the Department of State Health Services [**Texas Department of Health**] (department) or an agent of the department in connection with a report under this chapter are confidential and not subject to disclosure under Government Code, Chapter 552, and not subject to disclosure, discovery, subpoena, or other means of legal compulsion for their release by the department or its agents. For the purposes of these rules, all local health authorities are agents for the department.

(b) – (c) (No change.)

§§96.501, 96.601

§96.501. Waiver for Rural Counties.

(a) The Department of State Health Services [**Texas Department of Health**] (department) shall waive the application of Health and Safety Code, Chapter 81, Subchapter H, to a rural county if the department finds that the application of the Subchapter to county would be burdensome.

(b) Waivers granted under this section expire annually by December 31 [, **2001**].

(c) A “Rural County” is a county that:

(1) (No change.)

(2) has a population of more than 50,000 but:

(A) (No change.)

(B) was not, based on the 2000 [**1990**] federal census, completely included within an area designated as urbanized by the Bureau of the Census of the United States Department of Commerce.

(d) A request for a waiver under the provisions of this section shall be submitted in writing prior to January 1 annually [, **2001**] to the Assistant Commissioner, Prevention and Preparedness [**Associate Commissioner, Disease Control and Prevention**], 1100 West 49th Street, Suite G-401, Austin, Texas 78756.

Repeal.

~~§96.601. Effective Dates.~~

~~(a) The exposure control plan (plan) and the rules are effective September 1, 2000.~~

~~(b) Except as provided in §96.501 of this title (relating to Waiver for Rural Counties), a governmental unit shall comply with this chapter not later than January 1, 2001.~~