



## 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

#### **Bloodborne Pathogen Control**

Bloodborne Pathogens

(Contaminated Sharps Injuries, Needlestick Prevention)

The Department of State Health Services (department) adopts amendments to §§96.101, 96.201 – 96.203, 96.301 – 96.304, 96.401, 96.402, 96.501 and the repeal of 96.601. The amendments are adopted to be effective **July 23, 2006**.

The amendments and repeal 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 governmental entity employees to Bloodborne pathogens and to continue a registration program for needleless systems and sharps with engineered sharp injury protections; and House Bill 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sections continue to exist because rules on this subject are needed and required by law; except that §96.601 will be repealed because the rule is no longer necessary.

#### **Summary of Amendments**

Amendments to §96.101 add more components to the definitions; §§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 and 96.401 provide a new website; amendments to §§96.302 and 96.304 add a two-year period for registration and renewal fees; §§96.301 and 96.501 are amended to cease the granting of Undue Burden and Rural Counties waivers, legislation for granting the waivers has expired (Chapter 1411, 76<sup>th</sup> Legislature §26.02).

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§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) Blood--Human blood, human blood components, and products made from human blood.

(2) Bloodborne pathogens--Pathogenic microorganisms that are present in human blood and that can cause diseases in humans, and include:

(A) Hepatitis B virus (HBV);

(B) Hepatitis C virus (HCV); and

(C) Human immunodeficiency virus (HIV).

(3) Contaminated the presence or reasonably anticipated presence of blood or other potentially infectious material on an item or surface.

(4) Contaminated equipment--Any equipment used in the workplace that has been soiled with blood or other potentially infectious materials on an item or surface.

(5) Contaminated sharps injury--Any sharps injury that occurs with a sharp used or encountered in a health care setting that is contaminated with human blood or body fluids.

(6) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory that is:

(A) Recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

(7) Employee--An individual who works for a governmental unit or on premises owned or operated by a governmental unit whether or not he or she is directly compensated by the governmental unit.

(8) Employs--Engages the services of employees.

(9) Engineered sharps injury protection--A physical attribute that:

(A) is built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids and that effectively reduces the risk of an exposure incident by a mechanism, such as barrier creation, blunting, encapsulation, withdrawal, retraction, destruction, or another effective mechanism; or

(B) is built into any other type of needle device, into a nonneedle sharp, or into a nonneedle infusion safety securement device that effectively reduces the risk of an exposure incident.

(10) Exposure incident--A specific eye, mouth, other mucous membrane, nonintact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

(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) A political subdivision of this state, including any municipality, county, or special district; or

(B) any other institution of government, including an institution of higher education.

(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) Health care professional--A person whose legally permitted scope of practice allows him or her to independently evaluate an employee of a governmental unit and determine the appropriate interventions after an exposure incident; this would include hepatitis B vaccination and postexposure evaluation and follow up.

(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) Needleless system--A device that does not use a needle and that is used:

(A) to withdraw body fluids after initial venous or arterial access is established;

(B) to administer medication or fluids; or

(C) for any other procedure involving the potential for an exposure incident.

(17) Occupational exposure--A reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

(18) Other potentially infectious materials include:

(A) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(B) any unfixed tissue or organ (other than intact skin) from a human, living or dead; and

(C) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(19) Personal protective equipment--Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

(20) Regulated waste/special waste from health care-related facilities--Solid waste which if improperly treated or handled may serve to transmit an infectious disease(s) and which is composed of the following:

(A) animal waste;

(B) bulk blood, bulk human blood products, or bulk human body fluids;

(C) microbiological waste;

(D) pathological waste; or

(E) sharps.

(21) Sharp--An object used or encountered in a health care setting that can be reasonably anticipated to penetrate the skin or any other part of the body and to result in an exposure incident and includes:

(A) needle devices;

(B) scalpels;

- (C) lancets;
- (D) A piece of broken glass;
- (E) A broken capillary tube;
- (F) an exposed end of a dental wire; or
- (G) A dental knife, drill, or bur.

(22) Sharps injury--Any injury caused by a sharp, including a cut, abrasion, or needlestick.

(23) Universal precautions/standard precautions--Approaches to infection control as defined in Title 29 Code of Federal Regulation §1910.1030, Occupational Safety and Health Administration (OSHA), Bloodborne Pathogens Standard and Morbidity and Hospital Infection Control Practices Advisory Committee, Guideline for isolation precautions in hospitals published in *Infection Control Hospital Epidemiology*, 1996; 17:53-80, and *American Journal of Infection Control*, 1996; 24:24-52. According to the concept of universal precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other Bloodborne pathogens.

§96.201. Applicability.

(a) These minimum standards apply to a governmental unit that employs employees who:

(1) provide services in a public or private facility providing health care-related services, including home health care organizations; or

(2) otherwise have a risk of exposure to blood or other material potentially containing Bloodborne pathogens in connection with exposure to sharps.

(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, 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) Employees who are directly compensated by a governmental unit are subject to all provisions of this chapter. Employees who are subject through their private employer to the Occupational Safety and Health Administration (OSHA), Bloodborne Pathogens Standard and uncompensated employees are subject only to the log and reporting

provisions of §§96.401 of this title (relating to Sharps Injury Log), and 96.402 of this title (relating to Confidentiality Statement) unless otherwise required by contract.

#### §96.202. Exposure Control Plan.

(a) The exposure control plan (plan) developed by the Department of State Health Services (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.dshs.state.tx.us/idcu/health/bloodborne_pathogens/reporting/) or from the Department of State Health Services regional offices.

#### §96.203. Minimum Standards.

(a) This exposure control plan (plan) is provided by the Department of State Health Services (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) Employers should review the plan for particular requirements as applicable to their specific situation. Governmental units may modify the plan appropriately to their respective practice settings. Employers will need to include provisions relevant to their particular facility or organization in order to develop an effective, comprehensive exposure control plan specific to their facility or organization.

(c) Employers will annually review their exposure control plan, update when necessary, and document when accomplished.

#### §96.301. Safety Recommendations.

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

(b) Waivers shall not be granted. The provisions in the legislation, which allowed the department to grant waivers, have expired (Chapter 1411, 76th Legislature, §26.02).

(c) The use of a prefilled syringe that is approved by the Federal Food and Drug Administration may not be prohibited.

(d) Evaluation committee.

(1) At least half of the members of an evaluation committee established by a governmental unit to implement subsection (b) of this section must be employees who are health care workers who have direct contact with patients or provide services on a regular basis.

(2) Whenever possible, the governmental entity establishing the evaluation committee shall consider using committees with similar duties already in existence.

§96.302. Device Registration.

(a) The Department of State Health Services (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) Each needleless system device or sharps device with engineered sharps injury protection that is the subject of the department's device registration application shall be in conformance with all applicable premarket notification or premarket approval requirements established by the U.S. Food and Drug Administration (FDA) unless otherwise exempted from such requirements.

(c) Each device manufacturer who manufactures a needleless system device or sharps device with engineered sharps injury protection and who desires to register the device for the first time with the department shall apply for registration in accordance with the procedures found in §96.303 of this title (relating to Registration Procedures).

(d) If a device manufacturer introduces more than one needleless system device or sharps device with engineered sharps injury protection into commerce, the manufacturer shall register each device separately in order for the device to be included on a list maintained by the department.

(e) Each sharps device with engineered sharps injury protection that is the subject of the department's device registration application shall contain physical attributes consistent with those recognized as effective for engineered sharps injury protection, as defined in §96.101(9) of this title (relating to Definitions).

(f) The department may accept reports from authorities in other jurisdictions, including the FDA, to determine the extent of compliance with these sections and with the provisions of Health and Safety Code, Chapter 81, Subchapter H.

(g) The department shall register a needleless system device or sharps device with engineered sharps injury protection that meets the requirements of these sections.

(h) Registration of a needleless system device or sharps device with engineered sharps injury protection by the department does not constitute an endorsement or recommendation of such device.

(i) Registration certificates shall not be transferable from one device to another or from one device name to another. Any request for transfer of registration due to a change in ownership shall be made pursuant to the requirements in subsection (l) of this section.

(j) All device registration certificates shall expire two years from the date of issuance.

(k) Renewal of registration.

(1) Upon expiration of a device registration, the registration may be renewed by filing an application for renewal on a form prescribed by the department, accompanied by the appropriate renewal fee.

(2) The renewal registration certificate shall be valid for two years.

(3) The appropriate registration renewal form and renewal fee for each device should be submitted to the department not later than 30 days following the expiration date of the current device registration in order to maintain the device on the department's list of existing needleless system devices and sharps devices with engineered sharps injury protection.

(4) The department shall renew the registration of a needleless system device or sharps device with engineered sharps injury protection following receipt of the appropriate renewal form and renewal fee.

(l) The device manufacturer shall notify the department in writing of any change that would render the information required in the initial registration application no longer accurate. Upon receipt of a written notification involving a change, the department may update the information contained in its list of needleless system devices and sharps devices with engineered sharps injury protection in order to reflect the 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 (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, 1100 West 49th Street, Austin, Texas, 78756.

(b) The initial application for device registration shall include the following information:

- (1) name, model, common name, and available sizes of the device;
- (2) premarket notification or approval number assigned by the U.S. Food and Drug Administration, unless otherwise exempted;
- (3) name, mailing address, and telephone number of the device manufacturer;
- (4) name of the contact person for the device manufacturer;
- (5) designation as either a needleless system device or sharps device with engineered sharps injury protection;
- (6) if a sharps device with engineered sharps injury protection, a description of the physical attribute(s) that effectively reduces the risk of sharps injury; and
- (7) name and signature of the person responsible for submitting the device registration application.

§96.304. Registration Fees. The Department of State Health Services (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 shall be required for each device registered for a two-year period.
- (2) A renewal fee of \$2,000 shall be required for renewing the registration of each device for a two-year term.
- (3) Initial and renewal registration fees will be assessed to cover the costs associated with the review and processing of device registration applications and in the administration of these sections and are therefore nonrefundable.

§96.401. Sharps Injury Log.

- (a) The chief administrative officer for each facility within a governmental unit shall report, as required by this section, each employee, as defined in §96.101(7) of this title (relating to Definitions), who sustains a contaminated sharps injury, as defined in §96.101(5) of this title. The chief administrative officer of the governmental unit may designate an employee for each facility within the governmental unit to serve as the reporting officer.
- (b) Information concerning each contaminated sharps injury shall be recorded in a written or electronic sharps injury log which shall be maintained by a governmental unit, in accordance with Health and Safety Code, Chapter 81, Subchapter H, and this chapter.
- (c) The following information must be recorded in the sharps injury log:

- (1) name and address of facility where injury occurred;
- (2) name and phone number of the chief administrative officer or reporting officer;
- (3) date and time of the injury;
- (4) age and sex of the injured employee;
- (5) type and brand of sharp involved;
- (6) original intended use of the sharp;
- (7) whether the injury occurred before, during, or after the sharp was used for its original intended purpose;
- (8) whether the exposure was during or after the sharp was used;
- (9) whether the device had engineered sharps injury protection, as defined in §96.101(9)(A) and (B) of this title (relating to Definitions), and if yes, was the protective mechanism activated and did the exposure incident occur before, during, or after activation of the protective mechanism;
- (10) whether the injured person was wearing gloves at the time of the injury;
- (11) whether the injured person had completed a hepatitis B vaccination series;
- (12) whether a sharps container was readily available for disposal of the sharp;
- (13) whether the injured person received training on the exposure control plan during the 12 months prior to the incident;
- (14) the involved body part;
- (15) the job classification of the injured person;
- (16) the employment status of the injured person;
- (17) the location/facility/agency and the work area where the sharps injury occurred;  
and
- (18) A listing of the implemented needleless systems and sharps with engineered sharps injury protection for employees available within the governmental entity.

(d) Information contained in subsection(c)(1) - (17) of this section concerning each contaminated sharps injury shall be reported not later than ten working days after the end of the calendar month in which it occurred.

(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 (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 (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:

[http://www.dshs.state.tx.us/idcu/health/bloodborne\\_pathogens/reporting/](http://www.dshs.state.tx.us/idcu/health/bloodborne_pathogens/reporting/)

or from the Department of State Health Services regional offices.

#### §96.402. Confidentiality Statement.

(a) All information and materials obtained or compiled by the Department of State Health Services (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) The department shall make available, in aggregate form, the information described in Health and Safety Code §81.305(b) and this chapter, provided that the name and other information identifying the facility is deleted and the information is provided according to public health regions established by the department.

(c) All information and materials obtained or compiled by the department or an agent of the department in connection with this chapter, are considered information relating to cases or suspected cases of diseases or health conditions, and may be released only as allowed by Health and Safety Code §81.046.

#### §96.501. Waiver for Rural Counties.

Waivers shall not be granted. The provisions in the legislation, which allowed the department to grant waivers, have expired (Chapter 1411, 76th Legislature, §26.02).