ENGROSSED SUBSTITUTE SENATE BILL 6416

State of Washington 56th Legislature 2000 Regular Session

By Senate Committee on Health & Long-Term Care (originally sponsored by Senators Thibaudeau, Deccio, Wojahn, Rasmussen, Johnson, Franklin, B. Sheldon, Costa, Prentice, Sheahan, Fraser, Swecker, McAuliffe, Winsley, Kohl-Welles, Haugen, Benton, Spanel, McDonald and Oke)

Read first time 02/01/2000.

AN ACT Relating to needlesticks and sharps protections; adding a new section to chapter 49.17 RCW; and creating a new section.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** The legislature finds that opportunities to improve bloodborne pathogens standards arise when product engineering improvements result in safer medical devices.

NEW SECTION. **Sec. 2.** A new section is added to chapter 49.17 RCW to read as follows:

(1) The department shall, by March 1, 2001, adopt rules revising the bloodborne pathogens standard governing occupational exposure to blood and other potentially infectious materials. The rules must require product evaluation in accordance with subsection (3) of this section, beginning no later than April 1, 2001. The rules must also embody a bloodborne pathogens standard meeting the requirements of subsection (4) of this section.

(2) The definitions in this subsection apply to all rules regarding occupational exposure to bloodborne pathogens and other potentially infectious materials.

(a) "Bloodborne pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus, hepatitis C virus, and human immunodeficiency virus.

(b) "Engineering controls" means controls including, but not limited to, sharps disposal containers, needleless systems, and sharps with engineered sharps injury protection that isolate or remove the bloodborne pathogens hazard from the workplace.

(c) "Engineered sharps injury protection" means either:

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

(ii) A physical attribute built into any other type of needle device, or into a nonneedle sharp, that effectively reduces the risk of an exposure incident.

(d) "Front-line health care worker" means a nonmanagerial employee responsible for direct patient care with potential occupational exposure to sharps-related injuries.

(e) "Needleless system" means a device that does not use needles for:

(i) The withdrawal of body fluids after initial venous or arterial access is established;

(ii) The administration of medication or fluids; and

(iii) Any other procedure involving the potential for an exposure incident.

(f) "Sharp" means any 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, including, but not limited to, needle devices, scalpels, lancets, and broken capillary tubes.

(g) "Sharps injury" means any injury caused by a sharp, including, but not limited to, cuts, abrasions, or needlesticks.

(h) "Sharps injury log" means a written or electronic record satisfying the requirements of subsection (4)(b)(iii) of this section.

(3)(a) The rules adopted under subsection (1) of this section must require each employer to adopt a methodology for product review and

evaluation of available needleless systems and sharps with engineered sharps injury protections, including an evaluation of reliable sources of information from such sources as government agencies, employer organizations, labor organizations, and other sources deemed appropriate, to enable the employer to select the appropriate engineering controls in the categories listed below for implementation no later than the date required under subsection (4) of this section. The employer's methodology for review and evaluation must include input from front-line health care workers who will be engaged in the use of the devices in accordance with the provisions of subsection (4)(b) of this section, as well as other appropriate sources in the employer's organization. Product review and evaluation should include, but not be limited to, the following categories of devices as used in the employer's facilities:

(i) Intravenous catheters;

(ii) Intravenous access devices and intravenous connectors;

(iii) Vacuum tube blood collection devices;

(iv) Blood-drawing devices such as phlebotomy needle/tube holders, butterfly-type devices, and syringes;

(v) Syringes used for purposes other than blood drawing;

(vi) Suture needles;

(vii) Scalpel devices; and

(viii) Any other category of medical device used at the employer's facility where there is a sharps injury risk.

(b) For each category of device, product review and evaluation must be conducted with meaningful input from front-line health care workers representing areas in which they will be used, as well as infection control professionals and representatives of other disciplines as appropriate. In addition, the department, in consultation with the Washington state hospital association and other provider associations, shall determine means by which these associations can help employers meet the requirements of this subsection. The product evaluation period should continue for not less than six months from the date of commencement.

(4) The rules adopted under subsection (1) of this section must require each employer to develop a written exposure control plan to be completed no later than three months following the effective date of the rules, establish sharps injury logs no later than three months following the effective date of the rules, and implement engineering

controls as soon as possible but no later than nine months after the effective date of the rules. The rules must include, but are not limited to, the following:

(a) A requirement that the most effective available needleless systems and sharps with engineered sharps injury protection be included as engineering and work practice controls. However, needleless systems and sharps with engineered sharps injury protection are not required if:

(i) Such devices are not available in the marketplace;

(ii) The employer, with input from the evaluation committee, described in (b)(v) of this subsection, determines by means of objective product evaluation criteria that use of such devices may jeopardize patient safety if utilized for a class or type of procedure, or for a class or type of procedure when performed on a certain type of patient;

(iii) A certified or licensed health care worker directly involved in the patient's care determines, in the reasonable exercise of clinical judgment, that use of such devices will jeopardize the patient's safety or the success of the particular medical procedure involving the patient. A health care worker who makes such a determination must report, in accordance with the requirements of (b)(vi) of this subsection, the reasons for failing to use an approved needleless system or sharp with engineered sharps injury protection;

(iv) The employer can demonstrate by means of objective product evaluation criteria that use of such devices are not more effective in preventing exposure incidents than the alternative used by the employer; or

(v) The employer can demonstrate, with respect to an engineering control which has not been available in the marketplace for twelve months, that reasonably specific and reliable information is not available regarding the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining by means of objective product evaluation criteria whether the use of the engineering control will reduce the risk of exposure incidents occurring in the employer's workplace;

(b) A requirement that each employer develop and implement an effective written exposure control plan that includes, but is not limited to, procedures for:

(i) Identifying and selecting needleless systems and sharps with engineered sharps injury protection. Any procedure adopted should provide that the evaluation committee described in (b)(v) of this subsection will have meaningful input into the identification and evaluation of such devices;

(ii) Updating the written exposure control plan when necessary to reflect progress in implementing needleless systems and sharps with engineered sharps injury protection as determined by the evaluation committee described in (b)(v) of this subsection, but in no event less than once every year;

(iii) Recording information concerning exposure incidents in a sharps injury log, including, but not limited to, the following information, if known:

(A) The date and time of the exposure incident;

(B) The type and brand of sharp involved in the exposure incident; and

(C) The description of the exposure incident that includes:

(I) The job classification of the exposed employee;

(II) The department or work area where the exposure incident occurred;

(III) The procedure that the exposed employee was performing at the time of the incident;

(IV) How the incident occurred;

(V) The body part involved in the exposure incident;

(VI) If the sharp had engineered sharps injury protection, whether the protective mechanism was activated, and whether the injury occurred before the protective mechanism was activated, during activation of the mechanism, or after activation of the mechanism;

(VII) If the sharp had no engineered sharps injury protection, whether and how such a mechanism could have prevented the injury, as well as the basis for the assessment; and

(VIII) An assessment of whether any other engineering, administrative, or work practice control could have prevented the injury, as well as the basis for the assessment;

(iv) Ensuring that all front-line health care workers are trained in, and demonstrate their ability to use, engineering controls before they are introduced into the clinical setting;

(v) Establishment by the employer of an evaluation committee to advise the employer on the implementation of the requirements of this

section. At least half the members of the committee must be either front-line health care workers or representatives of employee organizations which represent front-line health care workers in job classifications impacted by the requirements of this section, including but not limited to nurses, medical assistants or nurses aides, technicians who handle or process sharps, phlebotomists, and physicians. An employer that is affiliated with, or affiliated for certain purposes with, a multistate or multilocation health care organization is in compliance with this section if it relies on an evaluation committee established by the organization centrally, so long as implementation of the advice of the centralized evaluation committee is accomplished in a manner that ensures communication with, training of, and feedback from affected staff of the local employer. Members of the evaluation committee must be provided demonstrations of the use of engineering controls and must be trained in product evaluation criteria prior to the commencement of any product evaluation; and

(vi) Ensuring all determinations pursuant to (a)(iii) of this subsection are reported in writing, including the date, time, patient, and procedure involved, and a statement of why the employee failed to use an approved needleless system or sharp with engineered sharps injury protections.

(5) In complying with this section, an employer with no more than ten full-time equivalent employees, responsible for direct patient care with potential occupational exposure to sharps related injuries, at any time during the calendar year immediately preceding the current calendar year may:

(a) Evaluate new technology through its own evaluation committee, as defined in subsection (4)(b)(v) of this section, a joint evaluation committee, established by multiple small business employers, that meets the requirements of subsection (4)(b)(v) of this section;

(b) Use a joint evaluation committee to develop and update the written procedure for identifying and selecting devices as required by subsection (4)(b)(i) and (ii) of this section; and

(c) Comply with the provisions of subsection (4)(b)(iii) of this section by recording the required sharps injury data in its OSHA 200 log.

(6) The department shall promulgate additional amendments to the bloodborne pathogens standard necessary to implement this section; and, to the extent that funds are available, evaluate the impact of this

section on the reduction of needlestick and sharps injuries and costs of employer operations.

(7) To assist employers in complying with the requirements of the bloodborne pathogens standard adopted under this section, the department shall compile and maintain a list of needleless systems and sharps with engineered sharps injury protection. The list may be developed from existing sources of information including, but not limited to, the federal food and drug administration, the federal centers for disease control, the national institute of occupational safety and health, and the United States department of veterans affairs.

(8) Nothing in this section provides an exemption or other basis of appeal in relation to the existing requirements of the bloodborne pathogens standard and any other requirements adopted under the authority of RCW 49.17.040 and 49.17.050.

(9) To the extent they exceed the existing bloodborne pathogens standard and any other requirements adopted under the authority of RCW 49.17.040 and 49.17.050, the requirements of this section do not apply to the practice of dentistry.

(10) The department shall consult with the Washington state hospital association and other provider associations to develop policy guidance, as effective as federal enforcement and consistent with existing bloodborne pathogens standards and any other requirements adopted under the authority of this chapter, which addresses compliance requirements prior to the implementation of regulations under this section.

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