

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: SB 222

SPONSOR: Senator Dyer

SUBJECT: Safety Standards for Public Health Care Employees

DATE: February 8, 2000 REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|-------------|----------------|-----------|-------------------------|
| 1. | <u>Liem</u> | <u>Wilson</u> | <u>HC</u> | <u>Fav/4 amendments</u> |
| 2. | _____ | _____ | _____ | _____ |
| 3. | _____ | _____ | _____ | _____ |
| 4. | _____ | _____ | _____ | _____ |
| 5. | _____ | _____ | _____ | _____ |

I. Summary:

Senate Bill 222 requires the Department of Health (DOH) to adopt a blood-borne-pathogen standard for public employees which requires needleless systems be implemented and that sharps with sharps-injury protection be used in all facilities that employ public employees, except where an evaluation committee determines that the use of such devices will jeopardize the safety of patients or employees with respect to a specific medical procedure. The bill requires the recording of incidents of exposure in a sharps injury log, consideration by the Department of Health of additional requirements to prevent sharps injuries or exposure incidents, and compilation and maintenance by the department of a list of existing needleless systems and sharps with engineered sharps-injury protection. This list shall be made available to public employers to assist them in complying with the requirements of the blood-borne-pathogen standard developed under this section.

The bill creates an undesignated section of law.

II. Present Situation:

Needle stick/sharps injuries

Health care workers use many types of needles and other sharp devices to provide patient care. Whenever a needle or other sharp device is exposed, injuries can occur and potentially fatal pathogens can be transmitted. Precise national or state level data are not available on the annual number of needle stick injuries among health care workers; however, the Centers for Disease Control and Prevention (CDC) estimate that 600,000 to 800,000 such injuries occur nationally each year. According to the Department of Health, there are no data regarding the number of needle stick injuries in Florida, but the annual rate of needle stick injury nation-wide is estimated to be 187 per 1000 health care workers.

Data from hospitals participating in the CDC National Surveillance System for Hospital Health Care Workers (NaSH) and from hospitals included in the University of Virginia's Exposure Prevention Information Network (EPINet) research database show that approximately 38% of sharps injuries occur during needle use and 42% occur after use and before disposal. The circumstances leading to a needle stick injury depend partly on the type and design of the device used. For example, needle devices that must be taken apart or manipulated after use (e.g., prefilled cartridge syringes and phlebotomy needle/vacuum tube assemblies) have been associated with increased injury rates. Needles attached to a length of flexible tubing (e.g., winged-steel needles and needles attached to intravenous (IV) tubing) are sometimes difficult to place in sharps containers and thus present another injury hazard. Injuries involving needles attached to IV tubing may occur when a health care worker inserts or withdraws a needle from an IV port or tries to temporarily remove the needle stick hazard by inserting the needle into a drip chamber, IV port or bag, or even bedding.

In addition to risks related to device characteristics, needle stick injuries are also related to certain work practices such as recapping, transferring a body fluid between containers, and failing to properly dispose of used needles in puncture-resistant sharps containers. Past studies of needle stick injuries have shown that 10% to 25% of such injuries occurred when recapping a used needle. Recapping by hand has been discouraged for some time and is prohibited under the Occupational Safety and Health Administration (OSHA) blood-borne-pathogens standard. Five percent of needle stick injuries in NaSH hospitals are still related to this practice. Injury may also occur when a health care worker attempts to transfer blood or other body fluids from a syringe to a specimen container (such as a vacuum tube) and misses the target. Also, if used needles or other sharps are left in the work area or are discarded in a sharps container that is not puncture resistant, a needle stick injury may occur.

Data from NaSH and the EPINet research database show that only a few needle types and other sharp devices are associated with the majority of injuries. Of nearly 5,000 injuries reported by hospitals participating in NaSH between June 1995 and July 1999, 62% were associated with hollow-bore needles, primarily hypodermic needles attached to disposable syringes (29%) and winged-steel (butterfly-type) needles.

Regulation of Workplace Safety

Workplace safety issues for private employers are regulated by the Occupational Safety and Health Act of 1970, as amended in 1990 and 1998, under the federal authority to regulate matters which affect interstate commerce. States are allowed to adopt standards only for occupational health or safety issues for which there is no standard in effect under the federal act. States which desire to assume responsibility for development and enforcement of occupational safety and health standards relating to any occupational safety or health issue with respect to which a Federal standard has been promulgated under the act may submit a state plan for the development of such standards and their enforcement to the Secretary of the United States Department of Labor. Twenty-three states have assumed this authority; Florida is not one of these. The Occupational Safety and Health Act excludes from federal regulation state government, or political subdivisions of a state.

Chapter 442, F.S., gives the Florida Department of Labor and Employment Security (DLES), Division of Safety, the authority to establish workplace safety standards for public sector employees. Section 442.20(2), F.S., allows the Division of Safety to adopt by rule the Federal OSHA standard for blood-borne pathogens at 29 C.F. R. Part 1910, subpart z, for public sector employees. In 1993, the Division promulgated rules which adopted the subpart as its rules. The Department of Health does not have statutory authority to regulate workplace safety in either the public or private sectors.

The federal standard for addressing needle stick injuries is the blood-borne-pathogens standard promulgated by OSHA at 29 CFR 1910.1030, which has been in effect since 1992. The standard applies to all occupational exposures to blood or other potentially infectious materials. Notable elements of this standard require the following:

- A written exposure control plan designed to eliminate or minimize worker exposure to blood borne pathogens
- Compliance with universal precautions (an infection control principle that treats all human blood and other potentially infectious materials as infectious)
- Engineering controls and work practices to eliminate or minimize worker exposure
- Personal protective equipment (if engineering controls and work practices do not eliminate occupational exposures)
- Prohibition of bending, recapping, or removing contaminated needles and other sharps unless such an act is required by a specific procedure or has no feasible alternative
- Prohibition of shearing or breaking contaminated needles (OSHA defines “contaminated” as the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface)
- Free hepatitis B vaccinations offered to workers with occupational exposure to blood borne pathogens
- Worker training in appropriate engineering controls and work practices
- Post-exposure evaluation and follow up, including post-exposure prophylaxis when appropriate.

In November 1999, OSHA revised and strengthened its internal compliance directive (guidance to be used by field inspectors) to reflect newer and safer technologies now available and to increase the employer’s responsibility to evaluate and use effective safer technologies.

DLES requires that a First Report of Injury Form (LES Form DWC-1) be completed and reported to the DLES Workers’ Compensation managed care provider. A copy of the form also is sent to the Department of Insurance, Division of Risk Management, Workers’ Compensation Claims. Records and medical treatment are managed through DLES’s Managed Care Workers’

Compensation Medical Case Manager. Databases and record keeping for workers' compensation injuries exist, although needle sticks and sharps injuries are not specifically coded.

Federal Legislation

The Health Care Worker Needlestick Prevention Act of 1999 (HR1899), was introduced in the U.S. House of Representatives on May 20, 1999 and in the Senate (S1140) on May 26, 1999. If passed, this legislation would require the Secretary of Labor to issue regulations to eliminate or minimize the significant risk of needle stick injuries to health care workers. The bills would amend the OSHA blood-borne-pathogens standard to require that all health care facilities use needle systems and sharps with engineered protection such as retractable needles. The bills would also require employees to create and keep a sharps injury log containing detailed information about any sharps injuries that occur. Employers would be required to adequately train direct health care workers on the use of needleless technologies and systems with engineered sharps protections. A new clearinghouse within the National Institute of Occupational Safety and Health (NIOSH) would be established to collect data on engineered safety technology that is designed to help prevent the risk of needle sticks and other sharps injuries. NIOSH would have access to the sharps injury logs to carry out these new tasks and the Institute is authorized \$15 million in new funding.

The United States Department of Health and Human Services would promulgate new regulations regarding conditions of participation in Medicare for those hospitals that are not covered by OSHA so that all hospitals across the country would be covered by these new blood-borne-pathogen requirements.

III. Effect of Proposed Changes:

Senate Bill 222 requires the Department of Health to adopt a blood-borne-pathogen standard for public employees which must be at least as stringent as the standard adopted by the federal Occupational Safety and Health Administration. The standard must include a requirement that needleless systems be implemented, and that engineered sharps-injury protection be used in all facilities that employ public employees except where an evaluation committee, established by the public employer and consisting of a majority of health care workers, determines by means of an objective evaluation of products that the use of such devices will jeopardize the safety of patients or employees with respect to a specific medical procedure.

The bill requires the recording of incidents of exposure in a sharps injury log and specifies the types of information to be recorded. The Department of Health is required to consider additional requirements to prevent sharps injuries or exposure incidents, such as training and educational requirements, measures to increase vaccinations, strategic placement of sharps containers as close to the work area as practical, and increased use of personal protective equipment.

The bill requires compilation and maintenance by the department of a list of existing needleless systems and sharps with engineered sharps-injury protection. The list may be developed from existing sources of information. This list shall be made available to public employers to assist them in complying with the requirements of the blood-borne-pathogen standard developed under this section.

The bill defines “public employer” as any employer who employs public employees who have occupational exposure to blood or other material that potentially contains blood-borne pathogens.

The bill defines “needleless systems” as devices that do not use needles for: 1) the withdrawal of body fluids after the initial venous or arterial access is established; 2) the administration of medication or fluids; or 3) any other procedure that involves the potential for an exposure incident.

The bill defines a “sharp” as any object used or encountered in a health care setting which can reasonably be 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, broken glass, broken capillary tubes, exposed ends of dental wires, dental knives, drills, and burrs.

The bill does not define an “exposure incident”.

The bill establishes an effective date of July 1, 2000.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The bill would significantly increase costs to local governments which employ public employees to provide health care services. Under the circumstances of this bill, Article VII, s. 18, Florida Constitution, requires that no county or municipality shall be bound by any general law requiring such local government to spend funds or to take action requiring the expenditure of funds unless the legislature has formally determined in the bill that such law fulfills an important state interest and the bill must pass by at least a 2/3 vote of the membership of each house of the legislature.

SB 222 does not contain the required finding of an important state interest.

B. Public Records/Open Meetings Issues:

The bill requires a standard to be developed which will govern public employees. The standard includes the recording of exposure incidents which includes information about public employees. Although the bill does not require the name of the employee who has been exposed to be recorded in the log, there will be sufficient information contained in the log to enable individuals to be identified. Since the employers are public entities, these records are public records subject to the provisions of Article I, s. 24, Florida Constitution.

Article I, s. 24, Florida Constitution, provides:

(a) Every person has the right to inspect or copy any public records made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. This section specifically includes the legislative, executive, and judicial branches of

government and each agency or department created thereunder; counties, municipalities, and districts; and each constitutional officer, board, and commission, or entity created pursuant to law or this Constitution.

In addition to the Florida Constitution, the Public Records Law¹ specifies conditions under which public access must be provided to governmental records of the executive branch and other governmental agencies. Section 119.07(1)(a), F.S., requires:

Every person who has custody of a public record shall permit the record to be inspected and examined by any person desiring to do so, at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public record or the custodian's designee. . . .

The Public Records Law states that, unless specifically exempted, all agency² records are to be available for public inspection. The term "public record" is broadly defined to mean:

All documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.³

The Florida Supreme Court has interpreted this definition to encompass all materials made or received by an agency in connection with official business which are used to perpetuate, communicate or formalize knowledge.⁴ All such materials, regardless of whether they are in final form, are open for public inspection unless made exempt.⁵

There is no public records exemption bill linked to SB 222.

C. Trust Funds Restrictions:

None.

¹Chapter 119, F.S.

²The word "agency" is defined in s. 119.011(2), F.S., to mean ". . . any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency." The Florida Constitution also establishes a right of access to any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf, except those records exempted by law or the Florida Constitution.

³Section 119.011(1), F.S.

⁴*Shevin v. Byron, Harless, Schaffer, Reid and Associates, Inc.*, 379 So. 2d 633, 640 (Fla. 1980).

⁵*Wait v. Florida Power & Light Company*, 372 So. 2d 420 (Fla. 1979).

D. Other Constitutional Issues:

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Approximately 1,585,000 syringes/needles were used in county health department immunization clinics last year to administer childhood immunizations. In addition, Department of Health (DOH) employees administer adult immunizations, prophylactic medications, emergency epidemic immunizations, and lab venipunctures. It is estimated that the latter accounts for the use of an additional 915,000 syringes/needles. There are no data on how many injections, immunizations, and lab venipunctures are administered through hollow-bore needles and syringes by non-DOH employees.

Based upon available data, DOH and the Department of Corrections together spent \$16,454 for syringe/needle purchases through the state prime vendor (4/1/98-3/31/99). This amount does not include syringe/needle purchases made from any other sources (e.g., direct, another wholesaler, contract, etc) nor does it include other public agencies, such as Department of Children and Families, and the State University System, which purchase their syringes/needles through other means.

Hollow-bore standard 3cc syringes cost approximately \$10 per 100 while the Vanish Point Syringe costs \$48 per 100. Adoption of a needleless system for the 2.5 million injections given annually in DOH settings would potentially increase the cost for syringes from \$250,000 to \$1,200,000 per year.

DOH purchases pre-filled syringes for specific medications and vaccines. Presently, manufacturers are not using retractable syringes for the pre-filled syringes or prepackaged medications with a disposable syringe. The bill would therefore have an impact on what products can be carried by the DOH central pharmacy as well as what items may be allowed for bid under the statewide pharmaceutical contract and the influenza program. Syringe units, if not retractable, will not be eligible for bid. Since, under the bill, manufacturers will be required to change to a pre-filled retractable syringe, costs are likely to increase.

In addition, DOH estimates that an additional .5 FTE would be required to supervise the development of a blood-borne-pathogen standard governing public employees and maintain a sharps injury log with the requirements set forth in the bill. Additional costs would be incurred related to the development of a training curriculum, materials, and the initial training

of approximately 3,000 DOH employees who use needles/sharps as a part of their job duties. This estimate does not include non-DOH employees. Annual training would also be necessary for new employees. Because database systems are already in place at DLES, there will not be a fiscal impact on developing a new tracking system.

DOH estimates that the total cost of the bill to that agency would be \$1,471,300.

The Department of Corrections estimates that the bill would increase costs by over \$1,000,000 annually. The department notes that this cost might be offset if the new system actually reduces worker compensation claims as a result of reduced injuries.

VI. Technical Deficiencies:

The bill requires the Department of Health to adopt a workplace standard for public employees. Current statutes assign this function to the Department of Labor and Employment Security, Division of Safety.

The bill does not provide rulemaking authority.

VII. Related Issues:

None.

VIII. Amendments:

#1 by Health, Aging and Long-Term Care:

Provides that the rules adopted to implement needleless systems and use of sharps with engineered sharps-injury protection may not prohibit the use of a prefilled syringe that is approved by the Federal Drug Administration and establishes a May 1, 2003 expiration date for this provision.

#2 by Health, Aging and Long-Term Care:

Replaces the words "Department of Health" with "Department of Labor and Employment Security," giving the Department of Labor and Employment Security the responsibility for adopting a blood-borne-pathogen standard governing public employees.

#3 by Health, Aging and Long-Term Care:

Replaces the words "Department of Health" with "Department of Labor and Employment Security," requiring the Department of Labor and Employment Security to consider additional requirements as part of the blood-borne-pathogen standard.

#4 by Health, Aging and Long-Term Care:

Replaces the words "Department of Health" with "Department of Labor and Employment Security," requiring the Department of Labor and Employment Security to compile and maintain a list of existing needleless systems and sharps with engineered sharps-injury protection.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
