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**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS**

BILL #: HB 193
RELATING TO: Public Health Care Employees/Safety
SPONSORS: Representative Kosmas and others
TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH REGULATION
 - (2) STATE ADMINISTRATION
 - (3) HEALTH & HUMAN SERVICES APPROPRIATIONS
 - (4) COUNCIL FOR HEALTHY COMMUNITIES
 - (5)
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I. SUMMARY:

This bill requires the Department of Health to adopt a blood-borne-pathogen standard governing public employees. The standard must be at least as stringent as the standard adopted by the federal Occupational Safety and Health Administration and must include, but need not be limited to a requirement that needleless systems, sharps with engineered sharps injury protection, and approved needle stick prevention technologies be used in all facilities that employ public employees, except in cases 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 that the use of such devices will jeopardize the safety of patients or employees with respect to a specific medical procedure.

This bill also requires that incidents of exposure be recorded in a sharps injury log. The Department of Health must compile a list of needleless systems, sharps with engineered sharps injury protection, and approved needlestick prevention technologies to be made available to the public to assist employers with complying with the standards adopted. It further requires the department to consider additional requirements as part of the blood-borne pathogen standard 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 Department of Health reports that the first year fiscal impact of this bill is approximately \$1.8 million. There will be a fiscal impact to the Department of Corrections and Department of Children and Family Services although the exact amount is unknown at this time. This bill may affect local governments that provide health care services. The cost to local governments is unknown.

This bill provides an effective date of July 1, 2001.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|--|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

This bill requires rulemaking to govern what types of needles and sharps may be used. Health care providers will be prohibited from making these decisions individually.

B. PRESENT SITUATION:

Congressional Acts:

The Blood-borne Pathogens Standard issued by the Occupational Safety and Health Administration in 1991 is credited with significantly reducing the risk of occupational exposure to blood borne pathogens such as the human immunodeficiency virus (HIV), hepatitis B and hepatitis C. Despite the progress that has been made, according to the Centers for Disease Control and Prevention (CDC), more than 380,000 injuries from contaminated sharps occur annually among health care workers in hospital settings. Estimates are as high as 600,000 - 800,0000 injuries annually when all health settings are considered. Since the publication of the Blood-borne Pathogens Standard in 1991, substantial progress has been made in the development of safer medical devices that when coupled with work practice controls, can substantially reduce the risk of occupational exposure to blood-borne pathogens.

The Needlestick Safety and Prevention Act of 2000, signed into law November 6, 2000, revises the Blood-borne Pathogens Standard, a regulation in effect under the Occupational Safety and Health Act of 1970 (OSHA), to require federal and private employers to consider using safer medical devices, designed to eliminate or minimize occupational exposure to blood-borne pathogens through needlestick and other injuries. The Act does not amend OSHA, but directs the Secretary of the U.S. Department of Labor (DOL) to make the changes in the Blood-borne Pathogens Standard, exactly as prescribed in the law, within six months of enactment. Published changes in the Federal Register become effective within 90 days of the publication date.

Major provisions include a requirement that most employers review and update exposure control plans to reflect changes in technology that eliminate or reduce such exposure; and document their consideration and implementation of appropriate commercially available and effective safer medical devices for such purpose. The Needlestick Safety and Prevention Act of 2000 requires employers to maintain a sharps injury log noting the type and brand of device used; where the injury occurred; and an explanation of the incident (exempting employers who are not required to maintain specified OSHA logs, such as State Agencies). As well, the Act stipulates that employers seek input on engineering and work practice controls from the affected health care workers (exempting employers, typically employers with 10 or less employees, who are not required to establish exposure control plans). In addition, it requires modifications of the standard to be in force until

superseded by regulations promulgated by the Secretary of the U.S. Department of Labor (DOL) under OSHA; and take effect without regard to the usual procedural requirements (Administrative Procedures Act).

By direction, the Secretary publishes the modifications to the Blood-borne Pathogens Standard in the Federal Register within six months of enactment. The modified standards, once published in the Federal Register, are effective 90 days after the date of publication. The Occupational Safety and Health Administration of the U.S. Department of Labor published a final rule implementing the provisions of this law on January 18, 2000 in the Federal Register (66 Fed. Reg. 5317). The rule will become effective April 18, 2001. Comments have been requested on the paperwork requirement provisions. Federal and private employers are subject to all OSHA regulations; the exception is small employers (10 or fewer employees) or state and local government, who are exempt from these requirements.

State of Florida

State agencies are required to document blood exposure incidents, although needlestick and sharps injuries are not coded specifically and kept in a central log. If an employee sustains a needlestick injury in connection with work duties, the Department of Labor and Employment Security requires a First Report of Injury Form to be completed and reported to the Department of Labor and Employment Security Worker's Compensation managed care provider. A copy of the form is also sent to the Department of Insurance, Division of Risk Management, and Worker's Compensation Claims.

According to the Florida Department of Labor and Employment Security, Division of Worker's Compensation, Bureau of Research and Education, between the years 1990-1999, only 1.2% of all Worker's Comp Claims filed in Florida were due to a puncture wound sustained while working (including, but not limited to needlestick punctures) that resulted in lost-time from work.

Public Health Employee/Industry Practice

Health care workers penetrate the skin and inject medication or fluids into the body as well as withdraw bodily fluids by using needles. Unfortunately, during the process of injecting or withdrawing fluids from a patient or carrying the needle, or while in the process of disposing the needle, the health care worker may accidentally penetrate his or her own skin and be "stuck" by the needle. Thereby, exposing the health care worker to any blood borne diseases, which may be fatal on occasion.

Statistical Data

While there are no statewide figures available, it is estimated that needle sticks injure 187 per 1000 health care workers nationwide annually. These accidental needle sticks injuries have led to the development and marketing of needless and protected needle systems. In the past five years alone, there have been over 15 papers published according to the Department of Health on the subject of blood-borne pathogens and needle sticks injuries. Seven of the fifteen papers included recommendations on the use of needless or protected needle systems. Three of these seven recommended that needless or protected needle systems be used. The remaining four papers opposed the use of needless or protected needle systems. Four of the fifteen papers were a result of clinical trial studies. Of the four, two were randomized controlled studies. One of these studies concluded that the rate of transmission of blood-borne pathogens was similar regardless of whether a needless or protected needle system was used. The other clinical trial concluded that the

reduction of injuries could be attributed to the needless and protected needle devices. Therefore, the effectiveness of needless and needle protected devices is still subject to debate.

Data from hospitals participating in the Centers for Disease Control and Prevention, 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 that are 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. In addition, if used needles or other sharps are left in the work area or 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.

In addition to the question of effectiveness, cost has been a significant factor in regards to the use of needleless or needle protected devices. The Department of Health reports that the cost of these systems is \$48 per 100 syringes compared to \$10 per 100 of the standard hollow-bore syringe. Adoption of a needleless system for the 2.5 million injections provided annually by the Department of Health would increase the cost from \$250,000 to \$1.2 million per year.

According to the proponents of this bill, the costs of treating each health care worker following a needlestick injury have been estimated between \$2,200 and \$3,800 for initial testing and treatment. The cost for annual drug therapy for a health care worker who contracts a blood-borne pathogen disease is estimated at \$20,000 to \$30,000. A lifetime of treating a health care worker who contracts Hepatitis C is estimated to cost up to \$500,000 and a lifetime of treating a health care worker who contracts HIV is estimated to cost up to \$1 million including lost wage payments and disability payments.

The California Occupational Safety and Health Standards Board estimated that California will have a net savings of \$106 million each year as a result of implementing the use of safe needles in all health care facilities. Although employers will spend \$185 million for the new, safer technology and

for expenses associated with record keeping, there is an anticipated savings of \$291 million in the costs for diagnosing and treating needlestick injuries.

Pursuant to s. 442.20(2), F.S., the Florida Department of Labor and Employment Security, Division of Safety currently has the statutory authority to regulate workplace safety for public employees in Florida. The state has adopted in rule 38I-20.003(1), F.A.C., the federal blood-borne pathogen standard, Subpart Z of the Occupational Safety and Health Standards, 29 C.F.R. Part 1920, which requires all job classes and specific jobs to be identified if they will be exposed to blood while completing assigned duties. For such positions, the employer must adopt an exposure control plan and offer the hepatitis B vaccine. State agencies also are required to use appropriate procedures for the disposal of needles and sharps.

C. EFFECT OF PROPOSED CHANGES:

According to the Department of Health, this bill would have a major impact on what products can be carried by the DOH central pharmacy as well as what items may be allowed for bid for the statewide pharmaceutical term contract and the influenza program. Syringe units, if not needleless systems or retractable, will not be eligible for bid. Because manufacturers will be required to change to a pre-filled retractable/needleless syringe systems, their costs will increase. Thus, there will be cost increases for pre-filled retractable syringes.

Additionally, pharmaceuticals are now packaged so that they are attached to disposable syringes, so there also would be a cost impact on these prepackaged items as well as syringe only purchases. This bill would require the creation of standards that do not now exist and would also require that a registry be created that is not in place. A statewide tracking system for compiling incident data would need to be created resulting in increased costs to the department.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Provides definitions for the terms "blood-borne pathogens", "engineered sharps injury protection", "needleless system", "public employer", "public employee", and "sharp".

Requires the Department of Health to adopt blood-borne-pathogen standards for public employees of the state or a political subdivision of the state, that must be at least as stringent as the standards adopted by the Occupational Safety and Health Administration and must include: a requirement that needless systems be implemented and that sharps with engineered sharps injury protection be used in all facilities that employ public employees. It provides for an exception to the needless system if it is determined, that use of such devices will jeopardize the safety and care of the patients.

Provides for information concerning incidents to exposures be recorded in an injury log that includes: date and time of exposure; the type and brand of sharp involved; and a description of the exposure. Provides that the Department of health consider additional requirements as part of the blood-borne-pathogen standard in order to prevent sharps injuries including but not limited to: training and educational requirements; measures to increase vaccinations, strategic placement of sharps containers as close to the work area as practical and increase in use of personal protective equipment.

Provides that the Department of Health must compile and maintain a list of existing needless systems that shall be available to assist public employers in complying with the requirements.

Section 2. Provides for an effective date of July 1, 2001.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DEPARTMENT OF HEALTH:

1. Non-Recurring or First-Year Start-Up Effects:

FY
2001-02

FY
2002-03

EXPENSE:

Organize workgroup/develop standards	\$ 458	
Schedule audio conference calls	\$ 106	
Curriculum Development/training manual	\$ 7,750	
Reproduction of training materials	\$ 1,800	
Development of video	\$10,559	
Distribution of materials	\$ 357	

Sub Total Expense

\$21,030

Standard DOH Expense Package

\$ 4,219

Computer/Workstation

\$ 1,500

Total Non-Recurring Costs

\$ 26,749

2. Recurring or Annualized Continuation Effects:

Salaries/Benefits:

25% Lapse

(.5 FTE) Registered Nurse Consultant, no travel
(1 Pay Grade 79)

\$ 19,722

\$26,822

Sub Total Salaries/Benefits:

\$ 19,722

\$26,822

Expenses:

Standard DOH Expense Package
(.5 Registered Nurse Consultant, no travel)

\$ 7,122

\$ 7,122

Needleless/retractable Syringes

\$1,400,000

\$1,400,000

Pharmaceutical with Needleless/retractable syringe

\$ 202,500

\$ 202,500

Data Collection, Systems Development & Analysis
(Electronic access)

\$ 150,000

\$ 150,000

Update and Evaluate

\$ 20,000

\$ 20,000

Sub Total Expense	\$1,779,612	\$1,779,612
Total Recurring Costs	\$1,779,612	\$1,806,434
3. Long-Run Effects Other Than Normal Growth:	\$0	\$0
4. Total Revenues and Expenditures	\$ 1,826,083	\$ 1,806,434

- The cost differences between the two types of syringes are significant. The cost for a standard syringes/needle unit is \$15 per 100. The cost for a comparable retractable (needleless) syringe is \$48 per 100.
- Other entities also give injectables through syringes/needles, such as local paramedics, EMT's, state hospitals, local jails, university school clinics, etc. The cost of these state entities has not been estimated.
- Florida does buy some needles and syringes through the state's prime vendor. However, many state entities could be using local purchase options to obtain these items from surgical companies. Therefore, we cannot accurately estimate the increased costs at the local level.
- The Prime Vendors currently available for DOH's use are Sun Surgical and Fisher Scientific that are on the DMS approved vendor list.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

This bill may affect local governments that provide health care services. The exact cost to local governments is unknown at this time.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

According to the Department of Health, 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. Manufacturers of the pre-filled syringes and prepackaged medications with disposal syringes will have to change to a needleless system. It is estimated that their costs will increase; thus, passing the increase costs on to the purchaser. The costs of the pre-filled retractable syringes and prepackaged medications with disposable syringes are an unknown at this time.

D. FISCAL COMMENTS:

There will be a fiscal impact on the Department of Corrections, Department of Juvenile Justice, and the Department of Children and Families to convert to needleless/retractable syringe systems. These agencies will need to estimate the fiscal impact of this bill.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill may require a city or county to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

No specific rulemaking authority is provided although this bill mandates that the Department of Health adopt standards with statewide implications.

C. OTHER COMMENTS:

According to the Department of Health:

“Ongoing research into the pros and cons on various systems is needed. The reliability and efficacy of the needleless syringe is very important. The research literature currently suggests that while needleless and protected needle systems are effective, cost-effectiveness is not well established. There are no data regarding the number of needlestick injuries in Florida, but the annual rate of needlestick injury nation-wide is estimated to be 187 per 1000 health care workers (McGormick et al 1991). DOH has found 15 papers on this subject that were published over the past 5 years, including four clinical trial studies. Of the four, two are randomized controlled trials (L'Ecuyer, 1996 and Orenstein, 1995), one is a multicenter trial (Lawrence, 1997) and one is a Phase 2 trial (Mendelson, 1998). The one randomized controlled trial concludes that the risk of transmission of blood borne pathogens is similar in both groups, the other concludes that no reduction of injuries can significantly be attributed to the devices and that a significant cost increase results. The two non-randomized controlled trials conclude that the devices are effective in reducing the injury rate. Seven papers included an opinion regarding whether or not to recommend such devices. Three papers included a recommendation in favor of the use of these devices (D'Arco, 1995; CDC/MMWR, 1997; and Yassi, 1995) and four were opposed (Cookson, 1998; Chodof, 1995; Kellerman, 1996; and McDonald, 1998).

There is no data on how many injections, immunizations, and lab venipuncture non-DOH employees administer through hollow-bore needles/syringes. **However, approximately 1,442,609 needles/syringes were used in county health departments for 07/1999 through 06/2000.** This data is based on doses of infant and adult immunizations, and emergency epidemic immunizations administered in county health departments and coded into the Client Information System Health Management Component (CISHMC) for programs 01 (state supplied vaccine) and 05 (non-state purchased vaccine). In addition, DOH employees administer some prophylactic medications that are packaged in pre-filled syringes and lab venipuncture systems. It is **estimated that the latter accounts for the use of an additional 3,329,700 syringes/needles.** Based upon available data, the DOH spent \$445,800 on syringe/needle purchases through the state prime vendor. 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, Department of Corrections, Department of Juvenile Justice, and the university systems, who purchase their syringes/needles through other means.”

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

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