

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|---|--|---|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 5. Empower families? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a "no" above, please explain:

The bill requires the Department of Health to compile and maintain a list of existing needless systems and sharps with engineered sharps-injury protection which shall be available to employers in health facilities and the general public. The Department asserts that this would require additional FTEs to compile and maintain this database, which would marginally increase the size of government.

B. EFFECT OF PROPOSED CHANGES:

The bill requires the Department of Health (DOH) to adopt in rule, the federal blood-borne-pathogen standard that would apply to DOH and to all public sector employers, except those whose compliance with the standards is required and regulated by federal law. The bill also requires DOH to create and maintain a list of existing needless systems and sharps with engineered sharps-injury protection.

Health care providers would need training on these standards. DOH would need to develop training programs and materials to administer the training. DOH would also be required to maintain a list of existing needless systems, which the department states, would require research and analysis by a Registered Nurse. However, the International Health Care Worker Safety Center at the University of Virginia has already created and maintains a list of these devices that is available on the Internet. See <http://www.med.virginia.edu/medcntr/centers/epinet/safetydevice.html>.

PRESENT SITUATION

Whenever a needle or other sharp instrument is used in a patient, there is a risk that the device can become contaminated by a blood-borne pathogen (i.e., bacteria or virus) carried by the patient. If a health care worker is accidentally punctured or cut by this contaminated device, there is a risk that the health care worker will contract the pathogen, sometimes creating life-threatening situations. The three pathogens that are of greatest concerns to health care workers include the human immunodeficiency virus (HIV), hepatitis-B (HBV), and hepatitis-C (HCV). Other possible pathogens include tuberculosis, syphilis, malaria, and herpes.

The Occupational Safety and Health Administration (OSHA) estimates that 5.6 million health care workers in the United States are at risk for occupational exposure to blood-borne pathogens in any given year. The annual, precise number of needlestick injuries to health care workers is not known, although the federal Centers for Disease Control and Prevention estimates that between 600,000 and 1,000,000 such incidents occur each year. The American Nurses Association (ANA) presents the following statistics concerning the transmission of blood-borne pathogens:

- ✓ The Centers for Disease Control has documented 32 cases of occupationally transmitted HIV in health care workers, including 12 nurses. They have investigated another 69 cases, including 14 nurses. To date, needlestick injury is the most common cause of occupationally-related HIV transmission.

- ✓ ANA reports that 8,700 health care workers contract hepatitis-B each year on the job and more than 200 die annually as a result. (A safe and effective vaccine is now available and many health care employers offer the vaccine for free to their employees).

Through the development and implementation of good work place safety procedures, including the use of “safe” needle technology, over 80% of needlestick injuries could be prevented. However, according to the ANA, less than 15% of hospitals use safer needle devices and systems. According to the Florida Department of Health, there are no data tracking the number of needlestick injuries in the state. The department simply relies on national estimates to assess the extent of the problem in Florida.

Health care workers use many types of needles and other sharp devices to provide patient care. Each use of one of these devices carries a risk of injury. The circumstances leading to an injury depend partly on when, how, and the type and design of the device used. 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 Network (EPINet) research database show that approximately 38 percent of sharp injuries occur during use, and 42 percent after use and before disposal. The vast majority of injuries were related to two types of devices: hollow-bore needles (62% of injuries); and hypodermic needles attached to disposable syringes and winged-steel (butterfly-type) needles (29%).

WORKPLACE SAFETY REGULATION

Congress passed the “Needlestick Safety and Prevention Act” (HR5178/S3067), and President Clinton signed it into law on November 6, 2000. The law requires:

1. Health care employers to document in their exposure control plan that they have evaluated and implemented safety-engineered sharp devices and needleless systems;
2. That exposure control plans be reviewed and updated on an annual basis;
3. Each health care facility to maintain a sharps injury log with detailed information;
4. Employers to solicit input from non-managerial (e.g., frontline) health care workers when identifying, evaluating, and selecting safety-engineered sharp devices; and,
5. Expansion of the definition of engineering controls.

The federal law and revised Bloodborne Pathogens Standard developed by OSHA (subpart Z of 29 C.F.R. part 1910), apply to any facility under federal OSHA where employees may be exposed to blood or other potentially infectious material, such as hospitals, long-term care facilities, clinical laboratories, physicians’ offices and dentists’ offices. States that desire to assume responsibility for development and enforcement of this standard may submit a state plan for development of such a standard and their enforcement strategy to the Secretary of the United States Department of Labor. As of June 2002, 21 states passed state needle safety legislation. This bill adds Florida to this list of states.

Since this bill was originally filed, the federal government passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Section 947 applies the OSHA blood-borne pathogens standard to certain hospitals, primarily public hospitals as define federal law. The law provides civil penalties for these hospitals if they do not comply with the standard. Because of this, public hospital advocates argue that they should be exempt from HB 17. They argue that without an exemption that they may be subject to dual regulation from OSHA and Florida’s DOH.

C. SECTION DIRECTORY:

Section 1. Amends s. 381.003, F.S., to require the Department of Health to promulgate a rule adopting the blood-borne pathogen standard. It also requires the department to compile and maintain a list of existing needleless systems and sharps with engineered sharps-injury protection for reference by employers in complying with this standard.

Section 2. Provides an effective date of July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The Department of Health (DOH) states that monies will be needed to fund 2.0 FTEs to lead the development and maintenance of a sharps-injury log with the requirements set forth in the bill, as well as the development of an electronic tracking system that maintains a list of safety engineered materials. Additional costs would be incurred related to the development of lists of existing needleless systems and sharps with engineered sharps-injury protection. A training curriculum, materials, and the initial training about safer devices for approximately 3,000 DOH employees who use needles/sharps as a part of their job duties is necessary. These requirements create a fiscal impact. The department projects a need for \$28,300 for non-recurring and first year start-up efforts, and \$155,502 (Year 1) and \$121,080 (Year 2) in recurring and annualized continuation effects, most of which is salaries.

The Department of Corrections provided a fiscal analysis and indicated that the fiscal effect on the agency "was indeterminate at this time."

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The United States General Accounting Office (GAO) found that the adoption of needles with safety features could reduce injuries by as much as 69,000 needlestick accidents each year, and coupled with other safety procedures, injuries could be reduced by a total of 177,000 needlesticks.

The GAO found that this would result in considerable costs savings, mostly from the reduced cost of treating those workers who have sustained injuries. The GAO compared the cost of changing to the new needleless technologies to the reduction in cost for treating workers with injuries (including lost work productivity). GAO predicts that the increased cost to purchase the needleless technologies would be between \$70 million and \$351 million annually, depending on the type of safety mechanism used. Except when the safety feature used was the most expensive available, the GAO found that the cost of changing to the higher cost technologies would save between \$9 million and \$90 million per year for hospitals.

D. FISCAL COMMENTS:

The Department of Health (DOH) states the legislation would require additional resources in terms of manpower (two full-time equivalents) to carryout, administer, and manage the requirements of the blood-borne pathogen standard. Furthermore, ongoing research into the pros and cons on various systems is needed. The reliability and efficacy of the needleless syringe is very important. They argue that the research literature currently suggests that while needleless and protected needle systems are

effective, cost-effectiveness is not well established. They also say that there exists 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 multi-center 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.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health states that they have sufficient rule making authority to implement this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 4, 2004, the Subcommittee on Health Services adopted an amendment to the bill, and then reported the bill favorably to the Committee on Health Care as amended. The amendment:

- Exempts public sector employers whose compliance with the standard is required and regulated by federal law.

On March 10, 2004, the Health Care Committee adopted the amendment recommended by the subcommittee and reported the bill favorably with a committee substitute.