

Legislative Analysis



PROHIBIT REUSE OF SINGLE-USE MEDICAL DEVICES

Mitchell Bean, Director
Phone: (517) 373-8080
<http://www.house.mi.gov/hfa>

House Bill 5825

Sponsor: Rep. Dian Slavens

House Committee: Health Policy

Senate Bill 528 (Substitute S-1)

Sponsor: Sen. Bill Hardiman

Senate Committee: Health Policy

Health Committee: Health Policy

Complete to 2-22-10

A SUMMARY OF HOUSE BILL 5825 AS INTRODUCED 2-17-10 AND SENATE BILL 528 AS PASSED BY THE SENATE 7-15-09

Senate Bill 528 would prohibit a person in a regulated health profession from using a previously-used, single use product more than once and establish administrative penalties for a violation. House Bill 5825 would include the penalty for a violation within the sentencing guidelines.

Senate Bill 528 would add a new section to the Public Health Code (MCL 333.20153) to prohibit a health care provider from knowingly reusing, recycling, refurbishing for reuse, or providing for reuse a single-use device. "Single use device" would mean a medical device intended for one use or one procedure on a human patient, and would include any device marked "single-use device."

A violation would be punishable by an administrative fine of not less than \$10,000 for a first offense and not less than \$20,000 for second and subsequent offenses. A violation by a health care professional would be considered a violation of Article 15 of the code and would subject the health care professional to administrative action (which can include additional fines and/or license sanctions) under Sections 16221(h) and 16226.

Applicability. The bill would apply to a health facility or agency that, or a health professional who, utilized single use devices in furnishing medical or surgical treatment or care to patients. "Health professional" would mean an individual registered, certified, or otherwise authorized to engage in a health profession under Article 15 of the Public Health Code, but would exclude dentists, dental hygienists, or dental assistants.

[The health professions regulated under Article 15 are chiropractic, dentistry, audiology, marriage and family therapy, medicine, nursing, optometry, osteopathic medicine and surgery, speech-language pathology, pharmacy, physical therapy, athletic training, massage therapy, podiatric medicine and surgery, nursing home administrator, counseling, psychology, occupational therapists, dietetics, sanitarians, social work, respiratory care, and veterinary medicine.]

Exemptions. The bill would not apply to a health care provider that utilized, recycled, or reprocessed for utilization, or provided for utilization, a single-use device that had been reprocessed by a federally registered and regulated reprocessor. "Reprocessed" would mean, with respect to a single-use device, an original device that had previously been used on a patient and had been subjected to additional processing and manufacturing for the purpose of additional use on a different patient.

The bill would also not apply to a health care provider that used an opened, but unused, single-use device that meets all of the following requirements:

- The sterile packaging on the single-use device had been opened and its sterility breached or compromised.
- The single-use device had not been used on a human patient and had not been in contact with blood or bodily fluids.
- The single-use device had been resterilized.

House Bill 5825 would amend the Code of Criminal Procedure (MCL 777.13n) to specify that the reuse of a single use medical product would be a Class D felony against the public safety with a maximum term of imprisonment of 10 years. The bill is tie-barred to Senate Bill 528. (However, see Background Information, later.)

FISCAL IMPACT:

Senate Bill 528 (S-1) as passed by the Senate may have fiscal implications for the Bureau of Health Professions and the Bureau of Health Systems in the Department of Community Health. Some additional costs may be incurred by the Department related to enforcement and violations for licensed health professions, and health facilities or agencies as defined in the Public Health Code. If these functions cannot be performed with existing personnel and resources, each additional regulatory FTE required to carry out the functions of the bill would be at a total cost of approximately \$80,000 - \$100,000.

If the changes made by the bill result in reduced infections or other consequential illness, over time the bill may have the fiscal impact of reducing state costs for related medical services for state employees and Medicaid participants.

Under the bill, any fines collected from violators would be deposited to the state's General Fund.

The impact of House Bill 5825, as introduced, is unclear as the sentencing guidelines prescribed in this bill for the reuse of a single use medical product are not consistent with the penalty provisions of the companion bill, Senate Bill 528, as it passed the Senate. Senate Bill 528 does not create a felony penalty; however, House Bill 5825 specifies that a violation is a Class D felony punishable by up to 10 years in prison.

If Senate Bill 528 were amended to be consistent with the provisions of House Bill 5825, the fiscal impact on state and local correctional systems would depend on how they

affected the numbers of felony convictions and severity of sentences. There are no data to indicate how many offenders might be affected by the bills. To the extent that the bills increased the numbers of felony sentences, the state could incur increased costs of incarceration or felony probation supervision. The average appropriated cost of prison incarceration is roughly \$33,000 per prisoner per year, a figure that includes various fixed administrative and operational costs. Costs of parole and probation supervision, exclusive of the cost of electronic tether, average about \$2,100 per supervised offender per year. To the extent that more offenders were sentenced to jail, affected counties could incur increased costs; jail costs vary with jurisdiction. The felony offense of reusing a single-use medical product would be a Class D offense against public safety. Exclusive of sentences for habitual offenders, the guidelines recommended minimum sentence for a Class D offense varies from 0-6 months, for which a nonprison sanction is required, to 43-76 months, for which a prison sentence is required.

Any increase in penal fine revenues would benefit local libraries, which are the constitutionally-designated recipients of those revenues.

BACKGROUND INFORMATION:

House Bill 5825 is identical to House Bill 4941 as passed by the House, and Senate Bill 528 is similar to House Bill 4940 as passed by the House. The primary difference between Senate Bill 528 as passed by the Senate and the House-passed version of House Bill 4940 is that the Senate bill in its current form creates an administrative fine as a penalty for a violation while the House bill makes a violation a 10-year felony.

Legislative Analyst: Susan Stutzky
Fiscal Analyst: Susan Frey
Margaret Alston
Bob Schneider

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.