



Senate Fiscal Agency
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BILL



ANALYSIS

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Senate Bill 528 (as enacted)
House Bill 5825 (as enacted)
Sponsor: Senator Bill Hardiman (S.B. 528)
Representative Dian Slavens (H.B. 5825)
Senate Committee: Health Policy (S.B. 528)
House Committee: Health Policy

PUBLIC ACT 25 of 2010
PUBLIC ACT 26 of 2010

Date Completed: 1-24-11

RATIONALE

In 2007, a Grand Rapids-area dermatologist was convicted of 33 counts of health care fraud. During the course of the investigation into his activities and the subsequent legal proceedings, it became known that the doctor frequently had engaged in the practice of reusing medical devices and supplies that were intended to be used on only one person, potentially exposing more than 13,000 patients to pathogens such as the human immunodeficiency virus (HIV) and the hepatitis B and C viruses. The doctor was sentenced to more than 10 years in prison for the fraud convictions and his medical license was revoked; there was no law, however, under which he could be subjected to a criminal charge or administrative fine for the unsanitary reuse practices. While some former patients sued him for medical malpractice, some people believed that civil remedies were not a sufficient deterrent or an adequate penalty for health care providers who would expose patients to serious health risks in this manner. It was suggested that the inappropriate reuse of single-use medical devices should be prohibited and violators should be subject to a sizeable administrative fine and criminal liability.

CONTENT

Senate Bill 528 amended the Public Health Code to prohibit a health care provider from knowingly reusing, recycling, refurbishing for reuse, or providing for reuse a single-use device, subject to certain exceptions; prescribe

a criminal penalty for a violation; and make a violation subject to administrative sanctions.

House Bill 5825 amended the Code of Criminal Procedure to include the reuse of a single-use medical device in the sentencing guidelines. The offense is a Class D felony against public safety punishable by up to 10 years in prison.

The bills took effect on March 26, 2010. House Bill 5825 was tie-barred to Senate Bill 528, which is described in further detail below.

Exceptions

The prohibition under Senate Bill 528 does not apply to a health care provider who uses, recycles or reprocesses for reuse, or provides for use a single-use device that has been reprocessed by an entity that is registered as a reprocessor and is regulated by the U.S. Food and Drug Administration (FDA); or to a provider who uses a used single-use device on the same human patient in an emergency situation.

In addition, the prohibition does not apply to a health care provider who uses an opened, but unused single-use device for which the sterility has been breached or compromised, subject to the following conditions:

- The device has not been used on a human patient and has not been in contact with blood or bodily fluids.
- The device has been resterilized.

Penalties

A health care provider who violates the prohibition is guilty of a felony punishable by imprisonment for up to 10 years and/or a maximum fine of \$50,000. A violation by a health professional is considered a violation of Article 15 (Occupations), and he or she is subject to administrative action under the Code.

(Article 15 authorizes the Department of Community Health to investigate activities related to the practice of a health profession by a licensee, registrant, or applicant for licensure or registration. The Department must report its findings to the appropriate disciplinary subcommittee. The subcommittee may impose sanctions if it finds the existence of certain grounds, including a violation of Article 15 or a rule promulgated under it. The sanctions include a reprimand; probation; denial, suspension, revocation, or limitation of a license or registration; restitution; community service; and a fine.

Also, the Department or a disciplinary subcommittee may request the Attorney General or a prosecuting attorney to prosecute a person for violating Article 15. As a rule, a violation is a misdemeanor punishable by imprisonment for up to 90 days and/or a maximum fine of \$100 for a first offense, or imprisonment for at least 90 days but not more than six months and/or a fine of at least \$200 but not more than \$500 for a second or subsequent offense.)

Definitions

The bill defines "single-use device" as a medical device that is intended for one use or procedure on a human patient, including any device marked "single-use device". "Reprocessed" means an original device that has been used previously on a human patient and has been subjected to additional processing and manufacturing for the purpose of additional use on a different human patient. The term includes the subsequent processing and manufacture of a reprocessed single-use device and any single-use device meeting this definition without regard to any description of the device used by its manufacturer or others, including a description using the term "recycled", "refurbished", or "reused", rather than "reprocessed". The term does not

include a disposable or single-use device that has been opened but not used on a person.

"Health care provider" means a health facility or agency or a health professional that uses single-use devices in furnishing medical or surgical treatment or care to patients. "Health professional" means an individual licensed, certified, or authorized to engage in a health profession under the Code, excluding dentists, dental hygienists, dental assistants, veterinarians, and veterinary technicians.

MCL 333.20153 (S.B. 528)
777.13n (H.B. 5825)

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Because the Public Health Code did not specifically prohibit the reuse of single-use medical devices, unscrupulous health care providers could put their financial interest above their patients' well-being without breaking the law. In the case of the Michigan dermatologist described above, some patients who contracted disease and suffered other ill effects were shocked and angered to learn that the doctor's conduct did not constitute a criminal act. Incidents of reuse of medical supplies, such as sutures and hypodermic syringes, by this doctor and physicians in several other states demonstrated the need for a clear prohibition and sufficient penalties for violators.

The bills provide a measure of protection for patients by prohibiting the reuse of single-use devices and prescribing incarceration and a stiff fine. Also, by specifying that improper reuse is a violation of Article 15, Senate Bill 528 authorizes the Department to impose administrative sanctions against a violator and seek criminal prosecution.

Senate Bill 528 also accommodates situations in which single-use devices are reused appropriately, i.e., they are reprocessed according to strict FDA standards, which will keep costs down without compromising patient safety.

FISCAL IMPACT

Senate Bill 528

The bill may require the Department of Community Health to increase oversight activities related to health facilities and providers, thus incurring some marginal costs. Any additional costs will likely be offset by administrative fines, which may be levied against those providers in violation of the bill's provisions.

House Bill 5825

The bill would have an indeterminate fiscal impact on State and local government. There are no data to indicate how many offenders will be convicted of the offense enacted by Senate Bill 528. An offender convicted of the Class D offense under the bills will receive a sentencing guidelines minimum sentence range of 0-6 months to 43-76 months, with a statutory maximum sentence of 10 years. Local governments will incur the costs of incarceration in local facilities, which vary by county. The State will incur the cost of felony probation at an annual average cost of \$2,000, as well as the cost of incarceration in a State facility at an average annual cost of \$33,000. Additional penal fine revenue will benefit public libraries.

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.