Senate Fiscal Agency
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BILL ANALYSIS

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Senate Bill 528 (Substitute S-1 as reported) *(as passed by the Senate)*
Sponsor: Senator Bill Hardiman
Committee: Health Policy

Date Completed: 6-16-09

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 The doctor was sentenced to more than 10 years in prison for the fraud convictions and his medical license was revoked; there was no law, however, under which he could be criminally charged or fined for the unsanitary reuse practices. While some former patients have sued him for medical malpractice, some people believe that civil remedies are not a sufficient deterrent or an adequate penalty for health care providers who would expose patients to serious health risks in this manner. It has been 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

The bill would amend 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; and to prescribe a fine for a violation.

The prohibition would not apply to a health care provider that used, recycled or reprocessed for reuse, or provided for use a single-use device that had been reprocessed by an entity that was registered as a reprocessor and was regulated by the U.S. Food and Drug Administration (FDA).

In addition, the prohibition would not apply to a health care provider that used an opened, but unused single-use device that met all of the following requirements:

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

A person who violated the prohibition would be subject to a fine of at least $10,000 for the first offense and at least $20,000 for the second and subsequent offenses. A violation by a health professional would be considered a violation of Article 15 (Occupations), and he or she would be 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.)

"Single-use device" would mean a medical device that is intended for one use or procedure on a human patient, including any device marked "single-use device". "Reprocessed" would mean 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 would include 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 would not include a disposable or single-use device that has been opened but not used on a person.

"Health care provider" would mean 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" would mean an individual licensed, certified, or authorized to engage in a health profession under the Code, excluding dentists, dental hygienists, or dental assistants.

Proposed MCL 333.20153

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 does not specifically prohibit the reuse of single-use medical devices, unscrupulous health care providers can 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 demonstrate the need for a clear prohibition and sufficient penalties for violators.

The bill would provide a measure of protection for patients by prohibiting the reuse of single-use devices and prescribing a stiff fine. By specifying that improper reuse would be a violation of Article 15, the bill would authorize the Department to impose administrative sanctions against a violator and seek criminal prosecution.

The bill also would accommodate situations in which single-use devices were reused appropriately, i.e., they were reprocessed according to strict FDA standards, which would keep costs down without compromising patient safety.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

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

Fiscal Analyst: Matthew Grabowski

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