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Senate Bill 528 (as introduced 4-30-09)
Sponsor: Senator Bill Hardiman
Committee: Health Policy

Date Completed: 6-10-09

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.

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 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.

"Single-use device" would mean a medical device that is intended for one use or procedure, including any device marked "single-use device". "Reprocessed" would mean an original device that has been used previously on a patient and has been subjected to additional processing and manufacturing for the purpose of additional use on a different 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

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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