



Senate Fiscal Agency
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Senate Bill 528 (Substitute S-1 as reported)
Sponsor: Senator Bill Hardiman
Committee: Health Policy

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 medical 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 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) of the Code, and he or she would be subject to administrative action by a disciplinary subcommittee of the Department of Community Health.

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.

Date Completed: 6-12-09

Fiscal Analyst: Matthew Grabowski