

Act No. 25
Public Acts of 2010
Approved by the Governor
March 26, 2010
Filed with the Secretary of State
March 26, 2010
EFFECTIVE DATE: March 26, 2010

**STATE OF MICHIGAN
95TH LEGISLATURE
REGULAR SESSION OF 2010**

Introduced by Senators Hardiman, Jansen, Anderson, Birkholz and Pappageorge

ENROLLED SENATE BILL No. 528

AN ACT to amend 1978 PA 368, entitled “An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to provide for the imposition of a regulatory fee; to provide for the levy of taxes against certain health facilities or agencies; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for the implementation of federal law; to provide for penalties and remedies; to provide for sanctions for violations of this act and local ordinances; to provide for an appropriation and supplements; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates,” (MCL 333.1101 to 333.25211) by adding section 20153.

The People of the State of Michigan enact:

Sec. 20153. (1) As used in this section:

(a) “Health care provider” means a health facility or agency or a health professional that utilizes single-use devices in furnishing medical or surgical treatment or care to human patients.

(b) “Health professional” means an individual licensed, certified, or authorized to engage in a health profession under article 15, but not including dentists, dental hygienists, or dental assistants under part 166 or veterinarians or veterinary technicians under part 188.

(c) “Original device” means a new, unused single-use device.

(d) “Reprocessed” means with respect to a single-use device, an original device that has previously been used on a human patient and has been subjected to additional processing and manufacturing for the purpose of additional use on a different human patient. Reprocessed includes the subsequent processing and manufacture of a reprocessed single-use device and any single-use device that meets the definition in this subdivision without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term “recycled”, “refurbished”, or “reused” rather than the term “reprocessed”. Reprocessed does not include a disposable or single-use device that has been opened but not used on a person.

(e) "Single-use device" means a medical device that is intended for 1 use or procedure on a human patient, including any device marked "single-use device".

(2) Except as otherwise provided in this section, a health care provider shall not knowingly reuse, recycle, refurbish for reuse, or provide for reuse a single-use device.

(3) This section does not apply to a health care provider that does any of the following:

(a) Utilizes, recycles or reprocesses for utilization, or provides for utilization a single-use device that has been reprocessed by an entity that is registered as a reprocessor and is regulated by the United States food and drug administration.

(b) Utilizes an opened, but unused single-use device for which the sterility has been breached or compromised and that meets all of the following requirements:

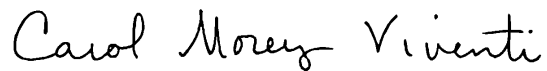
(i) The single-use device has not been used on a human patient and has not been in contact with blood or bodily fluids.

(ii) The single-use device has been resterilized.

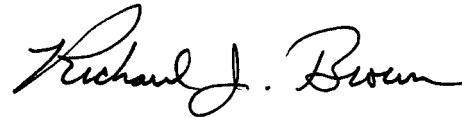
(c) Utilizes a used single-use device on the same human patient in an emergency situation.

(4) A health care provider that violates this section is guilty of a felony punishable by imprisonment for not more than 10 years or a fine of not more than \$50,000.00, or both. A violation of this section by a health professional is considered a violation of article 15 and that health professional is subject to administrative action under sections 16221(h) and 16226.

This act is ordered to take immediate effect.



Secretary of the Senate



Clerk of the House of Representatives

Approved

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Governor