

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.20153 Definitions; single-use device; reusing, recycling, or refurbishing prohibited; exceptions; violation as felony; penalty.

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.

History: Add. 2010, Act 25, Imd. Eff. Mar. 26, 2010

Popular Name: Act 368