

1 and manufacture of a reprocessed single-use device shall result in a device that is reprocessed
2 within the meaning of this definition, any single-use device that meets the definition under this
3 meaning shall be considered a reprocessed device without regard to any description of the device
4 used by the manufacturer of the device or other persons including a description that uses the term
5 "recycled" "refurbished" or "reused" rather than the term "reprocessed" but does not include, a
6 disposable or single-use medical device that has been opened but not used on a person;

7 (6) "Health Care Provider" means any state licensed facility, any licensed physician,
8 nurse practitioner, nurse midwife, physician's assistant, nurse, dentist or other health care
9 professional that utilizes single-use medical products in furnishing medical, surgical or dental
10 treatment or care to patients.

11 **23-16.5-3. Reuse of single-use of medical device prohibited.** -- (a) Except as provided
12 in this chapter a health care provider may not use a reprocessed single-use medical device on a
13 patient.

14 (b) A health care provider may not use a reprocessed single-use medical device on a
15 patient without the patient's consent as evidenced by a signed written notice required under this
16 section which shall be a permanent medical record of the patient.

17 **23-16.5-4. Written notice to patient.** -- (a) Except as provided under this chapter; a
18 health care provider shall provide each patient on admission or registration of a written notice that
19 describes: (i) the practices of the health care provider regarding reprocessed single-use medical
20 devices including the circumstances under which such reprocessed single-use devices are used
21 and the safeguards taken by the health care provider to ensure the safety of the patient under those
22 circumstances; and (ii) the potential risks of using reused single-use medical devices generally
23 and in the specific application.

24 (b) The notice required by this section shall provide the patient an opportunity to provide
25 or refuse consent to the use of reprocessed single-use medical devices on the patient and a
26 patient's refusal to consent shall not in any way limit the patient's access to health care including
27 with use of an original device.

28 (c) The notice shall: (i) be separate from all other documents provided to the patient; (ii)
29 be in plain language; (iii) provide a place to indicate the patient's refusal to consent if the patient
30 so chooses; (iv) provide a signature line for the patient; and (v) be approved by the department
31 including the adequacy of the notice itself and the adequacy of the description of potential risks
32 provided in the notice.

33 (d) A health care provider shall ensure that a signed notice required under this section is
34 made part of the permanent medical record of the patient.

1 (e) Except as provided under this chapter, on admission or registration of a patient, a
2 health care provider shall require the attending physician or the attending physician's designee to:
3 (1) describe verbally the contents of the notice required under this section to the patient, including
4 the patient's opportunity to provide or refuse consent to the use of reprocessed single-use medical
5 devices; (2) ensure that the patient understands the contents of the notice required; and (3) if
6 necessary arrange for an interpreter to facilitate the patient's comprehension of the notice required
7 in this section.

8 **23-16.5-5. Subsequent hospital admissions. --** If a health care provider has admitted or
9 registered a patient in compliance with this chapter, the health care provider is not required to
10 comply with this section during subsequent admissions or registrations of the same patient so
11 long as the health care provider verifies that the patient's provision or refusal of consent to the use
12 of reprocessed single-use medical devices is recorded in the permanent medical record of the
13 patient and unless the patient revokes consent in a subsequent written document provided to the
14 health care provider, any written revocation shall be deemed effective regardless of its form.

15 **23-16.5-6. Liability. --** A reprocessor who reconditions or reprocesses any single-use
16 medical device shall be liable for the safety and effectiveness of any reprocessed single-use
17 device except that a health care provider who fails to fulfill the informed patient consent
18 requirement under this chapter shall also be held liable. In no event shall an original manufacturer
19 be held liable for the use, safety or effectiveness of a reprocessed single-use device unless such
20 original manufacturer has expressly and specifically consented to the use of the reprocessed
21 device in that specific instance.

22 **23-16.5-7. Notification to the department of health. --** Notification of the department
23 must occur whenever a person performing the reuse, recycling, reprocessing, refurbishing for
24 reuse or providing for the reuse of a single-use medical device, reconditioning, or rebuilding a
25 single-use medical device becomes aware of information that suggests that a single-use medical
26 device that was reused, recycled, reprocessed, refurbished, reconditioned or rebuilt by a person or
27 entity may have: (a) caused or contributed to a death or serious injury; or (b) malfunctioned and
28 the single-use medical device or a similar device that would be reused, recycled, reprocessed, or
29 refurbished by a hospital or other entity on behalf of the hospital, would be likely to cause a death
30 or serious injury if the malfunction were to recur.

31 **23-16.5-8. Prima Facie Evidence. --** Failure of a reprocessor or health care provider to
32 comply with the provisions of this chapter is prima facie evidence that the reprocessing of the
33 device alone has rendered a reprocessed single-use device unreasonably dangerous and unfit for
34 its intended use.

1 **23-16.5-9. Penalty.** -- A person convicted of violating this section shall be fined not less
2 than ten thousand dollars (\$10,000) for a first offense and not less than twenty thousand dollars
3 (\$20,000) for a second or subsequent offense. Remedies provided under this chapter are not
4 exclusive of any other remedies that may be pursued against a reprocessor or health care provider.

5 SECTION 2. This act shall take effect upon passage.

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LC00337
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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N A C T
RELATING TO HEALTH AND SAFETY - MEDICAL DEVICES

- 1 This act would prohibit health care providers from reusing certain medical devices
- 2 without the express consent of the patient.
- 3 This act would take effect upon passage.

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LC00337
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