2008 -- S 2162

=======
LC01009
=======

S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2008

A N A C T

RELATING TO HEALTH AND SAFETY -- MEDICAL DEVICES

Introduced By: Senator Leo R. Blais

Date Introduced: January 31, 2008

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby amended by adding thereto the following chapter:

CHAPTER 16.5

PATIENTS RIGHT TO KNOW OF THE REUSE OF CERTAIN MEDICAL DEVICES

23-16.5-1. Title.– This chapter may be cited the "Patient's Right to Know of the Reuse of Certain Medical Devices Act."

23-16.5-2. Definitions. – As used in this chapter:

(1) "Single-use device" means a device that is intended for one use on a single patient during a single procedure including any device marked "single-use device";

(2) "Original device" means a new, unused single-use device;

(3) "Original manufacturer" means any person who designs, manufacturers, fabricates, assembles or processes a finished device which is new and has not been used in a previous medical procedure;

(4) "Reprocessor" includes, but is not limited to, a person who performs the functions of contract sterilization installation, relabeling, remanufacturing, repacking or specification development of reprocessed single-use devices;

(5) "Reprocessed" means with respect to a single-use device, an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of additional use on a different patient. The subsequent processing

and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition, any single-use device that meets the definition under this meaning shall be considered a reprocessed device 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" but does not include, a disposable or single-use medical device that has been opened but not used on a person;

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 2. This act shall take effect upon passage.

=======
LC01009
========

EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO HEALTH AND SAFETY -- MEDICAL DEVICES

***

This act would prohibit health care providers from reusing certain medical devices without the express consent of the patient.

This act would take effect upon passage.

=======
LC01009
=======