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HOUSE BILL NO. 768

Offered January 11, 2006
Prefiled January 10, 2006

A BILL to amend the Code of Virginia by adding sections numbered 32.1-135.3 and 54.1-2403.001, relating to hospitals and health care practitioners; use of reprocessed single-use medical devices; civil penalty.

Patron—Sickles

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding sections numbered 32.1-135.3 and 54.1-2403.001 as follows:

§ 32.1-135.3. Re-use of certain medical devices manufactured for a single use; civil penalty.

No hospital licensed under this chapter shall knowingly or willfully allow the re-use of medical devices manufactured for a single use by any of its personnel except as provided in § 54.1-2403.001. Violation of this section shall result in civil fines as provided in subsection J of § 54.1-2403.001.

§ 54.1-2403.001. Re-use of certain medical devices manufactured for a single use; civil penalty.

A. As used in this section:

"Board" means the Board of Health Professions.

"Health care provider" means any physician, nurse practitioner, nurse midwife, physician assistant, nurse, dentist, or other health care professional licensed under Title 54.1 who utilizes single-use medical products in furnishing medical, surgical, or dental treatment or care to patients.

"Original device" means a new, unused single-use device.

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

"Reprocessor" includes a person who performs the functions of contract sterilization installation, relabeling, remanufacturing, repacking, or specification development of reprocessed single-use devices.

"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.

"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."

B. Except as provided in this section a health care provider may not use a reprocessed single-use medical device on a patient. Under no circumstances shall a health care provider use a reprocessed, single-use needle or syringe.

C. 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.

D. Except as provided under this section, a health care provider shall provide each patient on admission or registration 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.

1. 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.

2. 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 Board, including the adequacy of

the notice itself and the adequacy of the description of potential risks provided in the notice.

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

E. Except as provided under this section, upon admission or registration of a patient, a health care provider shall require the attending physician or the attending physician's designee to: (i) 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; (ii) ensure that the patient understands the contents of the notice required; and (iii) if necessary, arrange for an interpreter to facilitate the patient's comprehension of the notice required in this section.

F. If a health care provider has admitted or registered a patient in compliance with this section, 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 health 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.

G. A reprocessor 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 section 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.

H. A health care provider shall notify the Board if he 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: (i) caused or contributed to a death or serious injury; or (ii) 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.

I. Failure of a reprocessor or health care provider to comply with the provisions of this section 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.

J. The Attorney General, an attorney of the Commonwealth, the attorney for a city, county or town, or any aggrieved patient may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, of the county, city or town, or of any aggrieved patient, to enjoin any violation of this section. The circuit court having jurisdiction may enjoin such violations, notwithstanding the existence of an adequate remedy at law. When an injunction is issued, the circuit court may impose a civil fine to be paid to the Literary Fund not to exceed $5,000. In any action under this section, it shall not be necessary that damages be proven. In the event that the injunction is violated, the circuit court may impose a civil fine to be paid to the Literary Fund not to exceed $10,000.

K. Remedies provided under this section are not exclusive of any other remedies that may be pursued against a reprocessor or health care provider.