SENATE . . . . . No. 1321

By Ms. Tucker, a petition (accompanied by bill, Senate, No. 1321) of Susan C. Tucker, John W. Scibak, Joyce A. Spiliotis, Steven A. Tolman and other members of the General Court for legislation relative to a patients' right to know of the re-use of certain medical devices manufactured for a single use. Public Health.

The Commonwealth of Massachusetts

In the Year Two Thousand and Five.

AN ACT RELATIVE TO A PATIENTS' RIGHT TO KNOW OF THE RE-USE OF CERTAIN MEDICAL DEVICES MANFACTURED FOR A SINGLE USE.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Chapter 111 of the General Laws is hereby amended by inserting after section 70G the following section:—

Section 70H. (A) The following words shall have the following meanings unless the context clearly requires otherwise:

"Single use device", a device that is intended for one use on a single patient during a single procedure including any device marked "single use device";

"Original device", a new unused single use device;

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

"Re-processor", includes, but is not limited to a person who performs the functions of contract sterilization installation, re-labeling, re-manufacturing re-packing or specification development of reprocessed single-use devices;

"Reprocessed", 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;

"Health Care Provider", any licensed facility under section 51, any licensed physician, nurse practitioner, nurse midwife, physician 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.

(B) Except as provided in this section a health care provider may not use a reprocessed single-use medical device on a patient.

(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)(a) 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.

(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 section, on admission or registration of a patient, a health care provider shall require the attending physician or the attending physician's designee to: (a) 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; (b) ensure that the patient understands the contents of the notice required; and, (c) 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 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.

(G) A re-processor 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) Notification to 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.

(I) Failure of a re-processor 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) A person convicted of violating this section shall be fined not less than $10,000 dollars for a first offense and not less than $20,000 dollars for a second or subsequent offense. Remedies provided under this section are not exclusive of any other remedies that may be pursued against a re-processor or health care provider.