THE SENATE
TWENTY-FIFTH LEGISLATURE, 2009
STATE OF HAWAII

S.B. NO. 361

JAN 23 2009

A BILL FOR AN ACT

RELATING TO SINGLE-USE MEDICAL DEVICES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 328, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"**PART**

SINGLE-USE MEDICAL DEVICES

§328-A Definitions. Whenever used in this part, unless the context requires otherwise:

"Facility" means any person or public or private institution, agency, clinic, or business, other than a hospital, that is authorized by state law to provide health care, services, or supplies to patients.

"Health care professional" means the same as that term is defined in section 321-313.

"Hospital" means an entity licensed as a hospital by state law.

"Informed consent" means a patient's written agreement to the use of reprocessed devices in treating and caring for that patient.

"Medical emergency" means a condition which, on the basis of the attending physician's good faith clinical judgment, so complicates a patient's medical condition as to necessitate the immediate provision of medical care to the patient in order to avert the patient's death, or for which a delay will create serious risk of substantial and irreversible impairment of major bodily function.

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

"Original manufacturer" means a person, company, or other entity that designs, manufactures, fabricates, assembles, or processes an original device.

"Reprocessed device" means an original device that has previously been used on a patient and has been subjected to additional processing or manufacturing for the purpose of additional use on a different patient. The subsequent processing or manufacture of an original device shall result in a device that is reprocessed within the meaning of this definition; and any single-use device that meets this definition shall be considered a reprocessed device without regard to any

description of the device used by the manufacturer, reprocessor, or other person or entity, including use of the term "recycled," "reprocessed," "refurbished," "reconditioned," "rebuilt," "reused," or other similar term rather than the term "reprocessed."

"Reprocessor" means a person, company, or other entity that undertakes procedures, including, but not limited to, additional processing, manufacturing, re-labeling, or re-packaging of an original device after it has been used on a patient for the purpose of creating a reprocessed device to be used on a different patient, or provides a means for the sale or distribution of reprocessed devices.

"Single-use device" means a medical device that is designed, manufactured, and approved by the federal Food and Drug Administration for one use on a single patient during a single procedure and is intended to penetrate normally sterile tissue or body spaces or contact intact mucous membranes during use.

§328-B Requirements for use of reprocessed devices. (a) A hospital, facility, or health care professional shall not use a reprocessed device in treating or caring for a patient without first having obtained the patient's informed consent in

accordance with the provisions of this part and on a form and in a manner prescribed by the director.

(b) A hospital or facility shall require that upon each admission or registration of a patient at a hospital or facility:

(1) A representative of the hospital or facility provide each patient with a written notice that describes:

(A) The policy of the hospital or facility regarding the use of reprocessed devices, including the circumstances under which these devices are used and the safeguards taken by the hospital or facility to ensure the safety of the patient under those circumstances; and

(B) The potential risks of using reprocessed devices generally and in the specific application for that patient, which shall be consistent with the contents of the informed consent form adopted by the director pursuant to section 328-C; and

(2) The patient's attending physician, or the attending physician's designee:

(A) Verbally describe the patient's opportunity to indicate the patient's consent or refusal to consent to the use of reprocessed devices in the patient's treatment or care, and explain the contents of the informed consent form adopted by the director pursuant to section 328-C; and

(B) Make every reasonable effort to ensure that the patient understands the informed consent form.

(c) Before providing treatment or care to a patient in a setting outside a hospital or facility, a health care professional shall:

(1) Provide the patient with a written notice that describes:

(A) The policy of the health care professional regarding the use of reprocessed devices, including the circumstances under which these devices are used and the safeguards

taken by the health care professional to ensure the safety of the patient under those circumstances; and

(B) The potential risks of using reprocessed devices generally and in the specific application for that patient, which shall be consistent with the contents of the informed consent form adopted by the director pursuant to section 328-C;

(2) Verbally describe the patient's opportunity to indicate the patient's consent or refusal to consent to the use of reprocessed devices in the patient's treatment or care, and explain the contents of the informed consent form adopted by the director pursuant to section 328-C; and

(3) Make every reasonable effort to ensure that the patient understands the informed consent form.

(d) The provisions of subsections (a), (b), and (c) of this section shall not apply in the case of a medical emergency.

(e) A patient's refusal to provide informed consent shall not, in any way, limit or restrict the patient's access to

health care, including treatment or care that includes the use of an original device.

(f) An informed consent form signed by a patient pursuant to this section shall be included as part of the patient's permanent medical record.

§328-C Informed consent forms. (a) The director shall adopt a uniform form for obtaining informed consent from patients as required by this part. The form shall be designed to ensure that the patient is provided with information, in a manner and in terms the patient understands, which is necessary for the patient to determine whether or not to provide written consent to the use of reprocessed devices in the patient's treatment or care. The information shall include, but not be limited to, any risk to the patient from the use of reprocessed devices and the fact that the patient's refusal to provide informed consent will not, in any way, limit or restrict the patient's access to health care. The form shall specifically include a notice to the patient that reprocessed devices may undergo structural or chemical degradation and may contain more than trace amounts of biological or chemical residue.

(b) The form shall include a place for the patient to indicate the patient's consent or refusal to consent to the use of reprocessed devices in the patient's treatment or care.

§328-D Duties of hospitals, facilities, and health care professionals. (a) A hospital or facility shall provide each health care professional who is employed or has privileges at the hospital or facility with:

(1) A written copy of the policy adopted by the hospital or facility on using reprocessed devices;

(2) Written notification if a specific device that the hospital or facility makes available for the use of the health care professional is a reprocessed device; and

(3) Written notification, prior to the rendering of a service or procedure with respect to a patient, as to whether the patient has provided informed consent.

(b) A health care professional who is employed or has privileges at a hospital or facility shall file a disclosure form with the hospital or facility acknowledging that the professional has been notified of the policy adopted by that hospital or facility on using reprocessed devices.

(c) A hospital or facility shall provide each health care professional who is employed or has privileges at the hospital or facility with the opportunity to file an objection to using a reprocessed device. A hospital or facility shall not force a health care professional who files such an objection to use a reprocessed device, and shall not take any disciplinary or punitive action against a health care professional for filing such an objection.

§328-E Inventory of reprocessed devices. (a) A patient's attending physician shall record in a patient's permanent medical record an inventory of each reprocessed device that is utilized in the course of a patient's treatment, and shall indicate the procedure in which the device was used. This inventory shall include, but not be limited to: the types of devices used; the name of the reprocessor that supplied each reprocessed device; and the reprocessor's lot number from which the reprocessed device came.

§328-F Monitoring of patients. A hospital or facility, at its own expense and in accordance with rules adopted by the director, shall, after discharge from the hospital or facility of a patient for whom a reprocessed device was utilized in the course of the patient's treatment at the hospital or facility,

monitor the patient for infection and disease. If the patient develops an infection or disease, the hospital or facility shall notify the department on a form and in a manner determined by the director, and the department shall investigate and determine if the infection or disease was caused by the use of a reprocessed device. The monitoring protocol prescribed by the director shall include, but not be limited to, the period of time that the patient is to be monitored and the tests that the monitoring is to include.

§328-G Duties of reprocessors; registration. (a) A reprocessor that provides reprocessed devices to a hospital, facility, or health care professional in the State shall:

(1) Register annually with the department, for which purpose the reprocessor shall furnish to the department such information as the director requires, including, but not limited to: the reprocessor's name, address, telephone number, list of corporate officers, and list of reprocessed devices that the reprocessor distributes to hospitals, facilities, or health care professionals; and

(2) Provide the department with:

(A) Notice of any inspection conducted by any governmental entity;

(B) A copy of any report produced as a result of that inspection;

(C) Immediate notice of any violation discovered through such an inspection;

(D) A copy of any remedial plan prepared by the reprocessor to correct any violation; and

(E) Proof of liability insurance or a statement that the reprocessor is self-insured.

(b) The director shall issue a distinct identification number to each reprocessor that registers with the department.

(c) The director may charge a registration fee to a reprocessor in an amount not to exceed the reasonable costs incurred by the department to process and record the registration.

(d) A reprocessor shall notify the director of any new reprocessed device not listed in its most recently filed annual registration, which the reprocessor intends to distribute to a hospital, facility, or health care professional in the State, by filing a registration amendment not less than thirty days prior to distribution of the new reprocessed device.

§328-H Liability; reporting. (a) A reprocessor shall be liable for the safety and effectiveness of each reprocessed device that the reprocessor distributes to a hospital, facility, or health care professional. In no event shall an original manufacturer be held liable for the use, safety, or effectiveness or a reprocessed device, unless the original manufacturer has expressly and specifically consented to the use of the reprocessed device in that specific instance.

(b) A person who recycles, reprocesses, refurbishes, reconditions, rebuilds, or otherwise provides for the reuse of a single-use device, and who comes to believe that the single-use device that was recycled, reprocessed, refurbished, reconditioned, rebuilt, or reused may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, shall report that information to the department on a form and in a manner prescribed by rule of the director.

(c) The failure of a reprocessor, health care professional, hospital, or facility to comply with the provisions of this section shall be prima facie evidence that the reprocessing of a single-use device has rendered the

reprocessed device unreasonably dangerous and unfit for its intended use.

§328-I Packaging standards; documentation. (a) The director shall develop standards for the packaging of reprocessed devices distributed to hospitals, facilities, and health care professionals in this State, in order to ensure an easy and immediate visual means of identifying a device as a reprocessed device, including, but not limited to, a requirement that the packaging bear a prominently displayed statement that the enclosed device is a reprocessed device.

(b) Each reprocessed device distributed to a hospital, facility, or health care professional in this State shall:

(1) Bear the identification number issued to the reprocessor by the department pursuant to section 328-G; and

(2) Include documentation as to:

(A) The source from which the reprocessor received the previously-used device;

(B) The number of times that device has been reprocessed; and

(C) A description of the means by which the device was reprocessed.

§328-J Lists of reprocessed devices. (a) The director shall develop a list of all reprocessed devices distributed to hospitals, facilities, and health care professionals based upon the information obtained by the department pursuant to section 328-G, and shall update the list whenever a reprocessor notifies the director that it intends to distribute additional reprocessed devices to a hospital, facility, or health care professional pursuant to section 328-G.

(b) The director shall make available to the public on the internet website of the department: the list of reprocessed devices distributed to hospitals, facilities, and health care professionals; and each annual registration and amendments filed by a reprocessor pursuant to section 328-G.

§328-K Violations; discipline. (a) A reprocessor, hospital, or facility that fails to comply with the provisions of this part, or any rules adopted pursuant thereto, shall be subject to a penalty as set forth in rules adopted by the director.

(b) A health care professional who fails to comply with the provisions of this part, or any rules adopted pursuant thereto, shall be subject to disciplinary action by the appropriate licensing board.

(c) The provisions of this part shall not be construed to preclude any other remedy that may be pursued against a reprocessor, hospital, facility, or health care professional.

§**328-L Rules.** The director shall adopt rules pursuant to chapter 91 to effectuate the purposes of this part."

SECTION 2. This Act shall take ~~effect~~ upon its approval.

INTRODUCED BY: _____

S.B. NO. 361

Report Title:
Single-Use Medical Devices; Reprocessed Devices; Informed Consent Prior to Use on a Patient

Description:
Requires health care providers to obtain informed consent from patients for use of certain reprocessed medical devices. Requires director of health to provide oversight and to adopt rules pertaining to reprocessed single-use devices.