SENATE BILL No. 1442

July 17, 2008, Introduced by Senators HARDIMAN, PAPPAGEORGE, BIRKHOLZ, JACOBS and JANSEN and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

(MCL 333.1101 to 333.25211) by adding section 20153.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

SEC. 20153. (1) AS USED IN THIS SECTION:

(A) "HEALTH CARE PROVIDER" MEANS A HEALTH FACILITY OR AGENCY OR A HEALTH PROFESSIONAL THAT UTILIZES SINGLE-USE DEVICES IN FURNISHING MEDICAL, SURGICAL, OR DENTAL TREATMENT OR CARE TO PATIENTS.

(B) "HEALTH PROFESSIONAL" MEANS AN INDIVIDUAL LICENSED, CERTIFIED, OR AUTHORIZED TO ENGAGE IN A HEALTH PROFESSION UNDER ARTICLE 15.

(C) "ORIGINAL DEVICE" MEANS A NEW, UNUSED SINGLE-USE DEVICE.

SENATE BILL No. 1442

(D) "ORIGINAL MANUFACTURER" MEANS ANY PERSON WHO DESIGNS, MANUFACTURES, FABRICATES, ASSEMBLES, OR PROCESSES A FINISHED MEDICAL DEVICE THAT IS NEW AND HAS NOT BEEN USED IN A PREVIOUS MEDICAL PROCEDURE.

(E) "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. REPROCESSED INCLUDES THE SUBSEQUENT PROCESSING AND MANUFACTURE OF A REPROCESSED SINGLE-USE DEVICE AND ANY SINGLE-USE DEVICE THAT MEETS THE DEFINITION IN THIS SUBDIVISION 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". REPROCESSED DOES NOT INCLUDE A DISPOSABLE OR SINGLE-USE DEVICE THAT HAS BEEN OPENED BUT NOT USED ON A PERSON.

(F) "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.

(G) "SINGLE-USE DEVICE" MEANS A MEDICAL DEVICE THAT IS INTENDED FOR 1 USE ON A SINGLE PATIENT DURING A SINGLE PROCEDURE, INCLUDING ANY DEVICE MARKED "SINGLE-USE DEVICE".

(2) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, A HEALTH CARE PROVIDER SHALL NOT USE A REPROCESSED SINGLE-USE DEVICE ON A PATIENT. A HEALTH CARE PROVIDER MAY USE A REPROCESSED SINGLE-USE DEVICE ON A PATIENT IF THE HEALTH CARE PROVIDER OBTAINS THE

PATIENT'S SIGNED, WRITTEN CONSENT AS REQUIRED UNDER THIS SECTION. IF OBTAINED UNDER THIS SECTION, THE HEALTH CARE PROVIDER SHALL INCLUDE THE SIGNED, WRITTEN CONSENT IN THE PERMANENT MEDICAL RECORD OF THE PATIENT.

(3) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, A HEALTH CARE PROVIDER SHALL PROVIDE TO EACH PATIENT ON ADMISSION OR REGISTRATION A WRITTEN NOTICE THAT DESCRIBES ALL OF THE FOLLOWING:

(A) THE PRACTICES OF THE HEALTH CARE PROVIDER REGARDING REPROCESSED SINGLE-USE DEVICES, INCLUDING THE CIRCUMSTANCES UNDER WHICH 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.

(B) THE POTENTIAL RISKS OF USING REPROCESSED SINGLE-USE DEVICES GENERALLY AND IN THE SPECIFIC APPLICATION WITH REGARD TO THAT PATIENT.

(4) THE WRITTEN NOTICE REQUIRED IN SUBSECTION (3) SHALL PROVIDE THE PATIENT AN OPPORTUNITY TO CONSENT OR REFUSE CONSENT TO THE USE OF REPROCESSED SINGLE-USE DEVICES ON THE PATIENT. THE HEALTH CARE PROVIDER SHALL NOT USE THE PATIENT'S REFUSAL TO CONSENT TO THE USE OF REPROCESSED SINGLE-USE DEVICES TO IN ANY WAY LIMIT THE PATIENT'S ACCESS TO HEALTH CARE, INCLUDING THE USE OF AN ORIGINAL DEVICE. THE WRITTEN NOTICE REQUIRED IN SUBSECTION (3) SHALL MEET ALL OF THE FOLLOWING REQUIREMENTS:

(A) BE SEPARATE FROM ALL OTHER DOCUMENTS PROVIDED TO THE PATIENT.

(B) BE IN PLAIN LANGUAGE.

(C) PROVIDE A PLACE TO INDICATE THE PATIENT'S CONSENT OR

REFUSAL TO CONSENT.

(D) PROVIDE A SIGNATURE LINE FOR THE PATIENT.

(E) BE APPROVED BY THE DEPARTMENT.

(5) A HEALTH CARE PROVIDER SHALL SUBMIT A WRITTEN NOTICE REQUIRED IN SUBSECTION (3) TO THE DEPARTMENT FOR APPROVAL BEFORE USE UNDER THIS SECTION. THE DEPARTMENT SHALL APPROVE A WRITTEN NOTICE SUBMITTED TO IT UNDER THIS SUBSECTION IF IT MEETS THE REQUIREMENTS OF SUBSECTIONS (3) AND (4), INCLUDING THE ADEQUACY OF THE NOTICE ITSELF AND THE ADEQUACY OF THE DESCRIPTION OF POTENTIAL RISKS PROVIDED IN THE NOTICE.

(6) EXCEPT AS OTHERWISE PROVIDED IN 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 DO ALL OF THE FOLLOWING:

(A) DESCRIBE VERBALLY THE CONTENTS OF THE WRITTEN NOTICE REQUIRED IN SUBSECTION (3) TO THE PATIENT, INCLUDING THE PATIENT'S OPPORTUNITY TO CONSENT OR REFUSE CONSENT TO THE USE OF REPROCESSED SINGLE-USE DEVICES.

(B) ENSURE THAT THE PATIENT UNDERSTANDS THE CONTENTS OF THE WRITTEN NOTICE REQUIRED IN SUBSECTION (3).

(C) IF NECESSARY, ARRANGE FOR AN INTERPRETER TO FACILITATE THE PATIENT'S COMPREHENSION OF THE WRITTEN NOTICE REQUIRED IN SUBSECTION (3).

(7) 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 IF THE HEALTH CARE

PROVIDER VERIFIES THAT THE PATIENT'S PROVISION OR REFUSAL OF CONSENT TO THE USE OF REPROCESSED SINGLE-USE 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. A HEALTH CARE PROVIDER SHALL COMPLY WITH A PATIENT'S WRITTEN REVOCATION, WHICH IS EFFECTIVE REGARDLESS OF ITS FORM.

(8) A REPROCESSOR IS LIABLE FOR THE SAFETY AND EFFECTIVENESS OF ANY REPROCESSED SINGLE-USE DEVICE. A HEALTH CARE PROVIDER WHO FAILS TO FULFILL THE INFORMED PATIENT CONSENT REQUIREMENT IN THIS SECTION IS ALSO LIABLE. AN ORIGINAL MANUFACTURER IS NOT LIABLE FOR THE USE, SAFETY, OR EFFECTIVENESS OF A REPROCESSED SINGLE-USE DEVICE UNLESS THE ORIGINAL MANUFACTURER HAS EXPRESSLY AND SPECIFICALLY CONSENTED TO THE USE OF THE REPROCESSED DEVICE IN THAT SPECIFIC INSTANCE.

(9) A PERSON SHALL PROMPTLY NOTIFY THE DEPARTMENT IF THE PERSON PERFORMING THE REUSE, RECYCLING, REPROCESSING, OR REFURBISHING FOR REUSE, OR PROVIDING FOR THE REUSE OF A SINGLE-USE DEVICE OR THE RECONDITIONING OR REBUILDING OF A SINGLE-USE DEVICE, BECOMES AWARE OF INFORMATION THAT SUGGESTS THAT A SINGLE-USE DEVICE THAT WAS REUSED, RECYCLED, REPROCESSED, REFURBISHED, RECONDITIONED, OR REBUILT BY A PERSON OR ENTITY MAY MEET ANY OF THE FOLLOWING:

(A) CAUSED OR CONTRIBUTED TO A DEATH OR SERIOUS INJURY.

(B) MALFUNCTIONED.

(C) THE SINGLE-USE DEVICE, OR A SIMILAR DEVICE, THAT WOULD BE REUSED, RECYCLED, REPROCESSED, OR REFURBISHED BY A HEALTH FACILITY OR AGENCY OR OTHER ENTITY ON BEHALF OF THE HEALTH FACILITY OR

AGENCY, WOULD BE LIKELY TO CAUSE A DEATH OR SERIOUS INJURY IF A MALFUNCTION WERE TO OCCUR.

(10) FAILURE OF A REPROCESSOR OR HEALTH CARE PROVIDER TO COMPLY WITH 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.

(11) A PERSON WHO VIOLATES THIS SECTION IS SUBJECT TO A FINE OF NOT LESS THAN $10,000.00 FOR THE FIRST OFFENSE AND NOT LESS THAN $20,000.00 FOR THE SECOND AND SUBSEQUENT OFFENSES. REMEDIES PROVIDED UNDER THIS SECTION ARE NOT EXCLUSIVE OF ANY OTHER REMEDIES THAT MAY BE PURSUED AGAINST A REPROCESSOR OR HEALTH CARE PROVIDER.