

SENATE BILL No. 528

April 30, 2009, Introduced by Senators HARDIMAN, JANSEN, ANDERSON, BIRKHOLZ and PAPPAGEORGE 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:

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

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

5 (B) "HEALTH PROFESSIONAL" MEANS AN INDIVIDUAL LICENSED,
6 CERTIFIED, OR AUTHORIZED TO ENGAGE IN A HEALTH PROFESSION UNDER
7 ARTICLE 15, BUT NOT INCLUDING DENTISTS, DENTAL HYGIENISTS, OR
8 DENTAL ASSISTANTS UNDER PART 166.

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

2 (D) "REPROCESSED" MEANS WITH RESPECT TO A SINGLE-USE DEVICE,
3 AN ORIGINAL DEVICE THAT HAS PREVIOUSLY BEEN USED ON A PATIENT AND
4 HAS BEEN SUBJECTED TO ADDITIONAL PROCESSING AND MANUFACTURING FOR
5 THE PURPOSE OF ADDITIONAL USE ON A DIFFERENT PATIENT. REPROCESSED
6 INCLUDES THE SUBSEQUENT PROCESSING AND MANUFACTURE OF A REPROCESSED
7 SINGLE-USE DEVICE AND ANY SINGLE-USE DEVICE THAT MEETS THE
8 DEFINITION IN THIS SUBDIVISION WITHOUT REGARD TO ANY DESCRIPTION OF
9 THE DEVICE USED BY THE MANUFACTURER OF THE DEVICE OR OTHER PERSONS,
10 INCLUDING A DESCRIPTION THAT USES THE TERM "RECYCLED",
11 "REFURBISHED", OR "REUSED" RATHER THAN THE TERM "REPROCESSED".
12 REPROCESSED DOES NOT INCLUDE A DISPOSABLE OR SINGLE-USE DEVICE THAT
13 HAS BEEN OPENED BUT NOT USED ON A PERSON.

14 (E) "SINGLE-USE DEVICE" MEANS A MEDICAL DEVICE THAT IS
15 INTENDED FOR 1 USE OR PROCEDURE, INCLUDING ANY DEVICE MARKED
16 "SINGLE-USE DEVICE".

17 (2) EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, A HEALTH
18 CARE PROVIDER SHALL NOT KNOWINGLY REUSE, RECYCLE, REFURBISH FOR
19 REUSE, OR PROVIDE FOR REUSE A SINGLE-USE DEVICE.

20 (3) THIS SECTION DOES NOT APPLY TO A HEALTH CARE PROVIDER THAT
21 UTILIZES, RECYCLES OR REPROCESSES FOR UTILIZATION, OR PROVIDES FOR
22 UTILIZATION A SINGLE-USE DEVICE THAT HAS BEEN REPROCESSED BY AN
23 ENTITY THAT IS REGISTERED AS A REPROCESSOR AND IS REGULATED BY THE
24 UNITED STATES FOOD AND DRUG ADMINISTRATION.

25 (4) THIS SECTION DOES NOT APPLY TO A HEALTH CARE PROVIDER THAT
26 USES AN OPENED, BUT UNUSED SINGLE-USE DEVICE THAT MEETS ALL OF THE
27 FOLLOWING REQUIREMENTS:

1 (A) THE STERILE PACKAGING ON THE SINGLE-USE DEVICE HAS BEEN
2 OPENED AND ITS STERILITY HAS BEEN BREACHED OR COMPROMISED.

3 (B) THE SINGLE-USE DEVICE HAS NOT BEEN USED ON A PATIENT AND
4 HAS NOT BEEN IN CONTACT WITH BLOOD OR BODILY FLUIDS.

5 (C) THE SINGLE-USE DEVICE HAS BEEN RESTERILIZED.

6 (5) A PERSON WHO VIOLATES THIS SECTION IS SUBJECT TO A FINE OF
7 NOT LESS THAN \$10,000.00 FOR THE FIRST OFFENSE AND NOT LESS THAN
8 \$20,000.00 FOR THE SECOND AND SUBSEQUENT OFFENSES.