

SUBSTITUTE FOR
SENATE BILL NO. 528

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 HUMAN 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.

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

10 (D) "REPROCESSED" MEANS WITH RESPECT TO A SINGLE-USE DEVICE,
11 AN ORIGINAL DEVICE THAT HAS PREVIOUSLY BEEN USED ON A HUMAN PATIENT

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

11 (E) "SINGLE-USE DEVICE" MEANS A MEDICAL DEVICE THAT IS
12 INTENDED FOR 1 USE OR PROCEDURE ON A HUMAN PATIENT, INCLUDING ANY
13 DEVICE MARKED "SINGLE-USE DEVICE".

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

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

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

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

27 (B) THE SINGLE-USE DEVICE HAS NOT BEEN USED ON A HUMAN PATIENT

1 AND HAS NOT BEEN IN CONTACT WITH BLOOD OR BODILY FLUIDS.

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

3 (5) A PERSON WHO VIOLATES THIS SECTION IS SUBJECT TO A FINE OF
4 NOT LESS THAN \$10,000.00 FOR THE FIRST OFFENSE AND NOT LESS THAN
5 \$20,000.00 FOR THE SECOND AND SUBSEQUENT OFFENSES. A VIOLATION OF
6 THIS SECTION BY A HEALTH PROFESSIONAL IS CONSIDERED A VIOLATION OF
7 ARTICLE 15 AND THAT HEALTH PROFESSIONAL IS SUBJECT TO
8 ADMINISTRATIVE ACTION UNDER SECTIONS 16221(H) AND 16226.