

HOUSE 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 OR VETERINARIANS OR VETERINARY
9 TECHNICIANS UNDER PART 188.

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

22 (A) UTILIZES, RECYCLES OR REPROCESSES FOR UTILIZATION, OR
23 PROVIDES FOR UTILIZATION A SINGLE-USE DEVICE THAT HAS BEEN
24 REPROCESSED BY AN ENTITY THAT IS REGISTERED AS A REPROCESSOR AND IS
25 REGULATED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

26 (B) UTILIZES AN OPENED, BUT UNUSED SINGLE-USE DEVICE FOR WHICH
27 THE STERILITY HAS BEEN BREACHED OR COMPROMISED AND THAT MEETS ALL

1 OF THE FOLLOWING REQUIREMENTS:

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

4 (ii) THE SINGLE-USE DEVICE HAS BEEN RESTERILIZED.

5 (C) UTILIZES A USED SINGLE-USE DEVICE ON THE SAME HUMAN
6 PATIENT IN AN EMERGENCY SITUATION.

7 (4) A HEALTH CARE PROVIDER THAT VIOLATES THIS SECTION IS
8 GUILTY OF A FELONY PUNISHABLE BY IMPRISONMENT FOR NOT MORE THAN 10
9 YEARS OR A FINE OF NOT MORE THAN \$50,000.00, OR BOTH. A VIOLATION
10 OF THIS SECTION BY A HEALTH PROFESSIONAL IS CONSIDERED A VIOLATION
11 OF ARTICLE 15 AND THAT HEALTH PROFESSIONAL IS SUBJECT TO
12 ADMINISTRATIVE ACTION UNDER SECTIONS 16221(H) AND 16226.