

SUBSTITUTE FOR  
HOUSE BILL NO. 4940

(As amended June 11, 2009)

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 [OR VETERINARIANS OR VETERINARY  
9 TECHNICIANS UNDER PART 188].

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 PATIENT AND

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

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

16 (3) THIS SECTION DOES NOT APPLY TO A HEALTH CARE PROVIDER THAT

17 [DOES ANY OF THE FOLLOWING:

18 (A) UTILIZES], RECYCLES OR REPROCESSES FOR UTILIZATION, OR PROVIDES  
19 FOR 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 [(B) UTILIZES

23 ] AN OPENED, BUT UNUSED SINGLE-USE DEVICE FOR WHICH THE  
24 STERILITY HAS BEEN BREACHED OR COMPROMISED AND THAT MEETS ALL OF  
25 THE FOLLOWING REQUIREMENTS:

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

(B) THE SINGLE-USE DEVICE HAS BEEN RESTERILIZED.

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1 [(C) UTILIZES A USED SINGLE-USE DEVICE ON THE SAME PATIENT IN AN  
EMERGENCY SITUATION.

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