

SENATE BILL 28

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2000 Regular Session
0lr0719
CF 0lr0995

(PRE-FILED)

By: **Senator Bromwell**
Requested: October 20, 1999
Introduced and read first time: January 12, 2000
Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Health - Reused Single-Use Medical Devices - Patient Consent Required**

3 FOR the purpose of prohibiting a hospital from using a certain type of medical device
4 under certain circumstances; requiring a hospital to provide a certain notice to
5 each patient on admission in a certain manner under certain circumstances;
6 requiring certain hospital personnel to perform specified duties under certain
7 circumstances; requiring a certain document to be made a part of the permanent
8 medical record of a patient; providing a penalty for each violation of this Act;
9 requiring the Department of Health and Mental Hygiene to adopt certain
10 regulations; providing for the effect of this Act; defining a certain term; and
11 generally relating to the consent required for the use of certain medical devices.

12 BY adding to
13 Article - Health - General
14 Section 19-353
15 Annotated Code of Maryland
16 (1996 Replacement Volume and 1999 Supplement)

17 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
18 MARYLAND, That the Laws of Maryland read as follows:

19 **Article - Health - General**

20 19-353.

21 (A) (1) IN THIS SECTION, "REUSED SINGLE-USE MEDICAL DEVICE" MEANS A
22 MEDICAL DEVICE THAT HAS BEEN:

23 (I) DESIGNATED AS DISPOSABLE OR FOR A SINGLE USE BY THE
24 MANUFACTURER OF THE DEVICE, THE HOSPITAL, THE DEPARTMENT, OR A FEDERAL
25 GOVERNMENTAL UNIT; AND

26 (II) USED ON ANOTHER INDIVIDUAL.

1 (2) IN THIS SECTION, "REUSED SINGLE-USE MEDICAL DEVICE" DOES
2 NOT INCLUDE A DISPOSABLE OR SINGLE-USE MEDICAL DEVICE THAT HAS BEEN
3 OPENED BUT NOT USED ON AN INDIVIDUAL.

4 (B) EXCEPT AS PROVIDED IN THIS SECTION, A HOSPITAL MAY NOT USE A
5 REUSED SINGLE-USE MEDICAL DEVICE ON A PATIENT.

6 (C) A HOSPITAL MAY NOT USE A REUSED SINGLE-USE MEDICAL DEVICE ON A
7 PATIENT WITHOUT THE PATIENT'S CONSENT, AS EVIDENCED BY A SIGNED WRITTEN
8 NOTICE REQUIRED UNDER THIS SECTION THAT IS PART OF THE PERMANENT
9 MEDICAL RECORD OF THE PATIENT.

10 (D) (1) EXCEPT AS PROVIDED UNDER SUBSECTION (F) OF THIS SECTION, A
11 HOSPITAL SHALL PROVIDE EACH PATIENT, ON ADMISSION OR REGISTRATION, WITH
12 A WRITTEN NOTICE THAT DESCRIBES:

13 (I) THE PRACTICES OF THE HOSPITAL REGARDING REUSED
14 SINGLE-USE MEDICAL DEVICES; AND

15 (II) THE POTENTIAL RISKS OF USING REUSED SINGLE-USE
16 MEDICAL DEVICES.

17 (2) THE NOTICE DESCRIBED IN PARAGRAPH (1) OF THIS SUBSECTION
18 SHALL PROVIDE THE PATIENT AN OPPORTUNITY TO PROVIDE OR REFUSE CONSENT
19 TO THE USE OF REUSED SINGLE-USE MEDICAL DEVICES ON THE PATIENT.

20 (3) THE NOTICE DESCRIBED IN PARAGRAPH (1) OF THIS SUBSECTION
21 SHALL:

22 (I) BE SEPARATE FROM ALL OTHER DOCUMENTS PROVIDED TO
23 THE PATIENT;

24 (II) BE IN PLAIN LANGUAGE;

25 (III) PROVIDE A SIGNATURE LINE FOR THE PATIENT; AND

26 (IV) BE APPROVED BY THE DEPARTMENT.

27 (4) A HOSPITAL SHALL ENSURE THAT A SIGNED NOTICE REQUIRED
28 UNDER PARAGRAPH (1) OF THIS SUBSECTION IS MADE PART OF THE PERMANENT
29 MEDICAL RECORD OF THE PATIENT.

30 (E) EXCEPT AS PROVIDED UNDER SUBSECTION (F) OF THIS SECTION, ON
31 ADMISSION OR REGISTRATION OF A PATIENT, A HOSPITAL SHALL REQUIRE THE
32 ATTENDING PHYSICIAN OR THE ATTENDING PHYSICIAN'S DESIGNEE TO:

33 (1) DESCRIBE VERBALLY THE CONTENTS OF THE NOTICE REQUIRED IN
34 SUBSECTION (D) OF THIS SECTION TO THE PATIENT, INCLUDING THE PATIENT'S
35 OPPORTUNITY TO PROVIDE OR REFUSE CONSENT TO THE USE OF REUSED
36 SINGLE-USE MEDICAL DEVICES;

1 (2) ENSURE THAT THE PATIENT UNDERSTANDS THE CONTENTS OF THE
2 NOTICE REQUIRED IN SUBSECTION (D) OF THIS SECTION; AND

3 (3) IF NECESSARY, ARRANGE FOR AN INTERPRETER TO FACILITATE THE
4 PATIENT'S COMPREHENSION OF THE NOTICE REQUIRED IN SUBSECTION (D) OF THIS
5 SECTION.

6 (F) IF A HOSPITAL HAS ADMITTED OR REGISTERED A PATIENT IN
7 COMPLIANCE WITH THIS SECTION, THE HOSPITAL IS NOT REQUIRED TO COMPLY
8 WITH SUBSECTIONS (D) AND (E) OF THIS SECTION DURING SUBSEQUENT
9 ADMISSIONS OR REGISTRATIONS OF THE SAME PATIENT SO LONG AS THE HOSPITAL
10 VERIFIES THAT THE PATIENT'S PROVISION OR REFUSAL OF CONSENT TO THE USE OF
11 REUSED SINGLE-USE MEDICAL DEVICES IS RECORDED IN THE PERMANENT
12 MEDICAL RECORD OF THE PATIENT.

13 (G) A HOSPITAL THAT VIOLATES THIS SECTION IS SUBJECT TO A FINE NOT TO
14 EXCEED \$10,000 FOR EACH VIOLATION.

15 (H) THIS SECTION DOES NOT LIMIT OR AVOID ANY LIABILITY OF A HOSPITAL
16 ARISING OUT OF THE USE OF A REUSED SINGLE-USE MEDICAL DEVICE.

17 (I) THE DEPARTMENT SHALL ADOPT REGULATIONS TO IMPLEMENT THIS
18 SECTION.

19 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
20 October 1, 2000.