



103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

HB1001

Introduced 1/12/2023, by Rep. Mary E. Flowers

SYNOPSIS AS INTRODUCED:

New Act

110 ILCS 330/8h new

210 ILCS 5/10h new

210 ILCS 85/11.9 new

Creates the Medical Device Safety Act. Provides that (i) all medical devices to be used by, surgically applied to, or surgically implanted within a patient be under warranty, regardless of the severity of the patient's medical condition necessitating the device, (ii) all persons and entities that produce, sell, offer for sale, or provide medical devices to be used by, surgically applied to, or surgically implanted within a patient are liable for all costs to the patient for the replacement of each medical device if the medical device malfunctions due to no fault of the patient, and (iii) all hospitals and ambulatory surgical treatment centers shall waive the costs charged to patients for follow-up surgeries that result from defective medical devices, regardless of whether or not those defective medical devices are capable of being implanted. Amends the University of Illinois Hospital Act, the Ambulatory Surgical Treatment Center Act, and the Hospital Licensing Act. Requires that the University of Illinois Hospital, all ambulatory surgical treatment centers, and all hospitals licensed under the Hospital Licensing Act waive the costs charged to patients for follow-up surgeries that result from previous surgical errors. Effective immediately.

LRB103 04880 CPF 49890 b

1 AN ACT concerning regulation.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 1. Short title. This Act may be cited as the
5 Medical Device Safety Act.

6 Section 5. Definition. In this Act:

7 "Medical device" has the same meaning as defined in
8 Section 3 of the Pharmacy Practice Act.

9 Section 10. Medical device warranty; cost of replacement;
10 cost of follow-up surgeries.

11 (a) All medical devices to be used by, surgically applied
12 to, or surgically implanted within a patient in this State on
13 or after the effective date of this Act, regardless of whether
14 or not those medical devices are capable of being implanted,
15 must be under warranty, regardless of the severity of the
16 patient's medical condition necessitating the medical device.

17 (b) All persons and entities that produce, sell, offer for
18 sale, or provide medical devices to be used by, surgically
19 applied to, or surgically implanted within a patient in this
20 State on or after the effective date of this Act shall be
21 liable for all costs for the replacement of each medical
22 device to be used by, surgically applied to, or surgically

1 implanted within a patient on or after the effective date of
2 this Act, regardless of whether or not that device is capable
3 of being implanted, if the device malfunctions due to no fault
4 of the patient.

5 (c) All hospitals licensed under the Hospital Licensing
6 Act or organized under the University of Illinois Hospital
7 Act, and all ambulatory surgical treatment centers licensed
8 under the Ambulatory Surgical Treatment Center Act, must waive
9 the costs charged to patients for follow-up surgeries that
10 result from defective medical devices, regardless of whether
11 or not those defective medical devices are capable of being
12 implanted.

13 Section 900. The University of Illinois Hospital Act is
14 amended by adding Section 8h as follows:

15 (110 ILCS 330/8h new)

16 Sec. 8h. Waiver of surgical costs. The University of
17 Illinois Hospital shall waive the costs charged to patients
18 for any follow-up surgery that results from a previous
19 surgical error that occurred at a University of Illinois
20 Hospital location.

21 Section 905. The Ambulatory Surgical Treatment Center Act
22 is amended by adding Section 10h as follows:

1 (210 ILCS 5/10h new)

2 Sec. 10h. Waiver of surgical costs. An ambulatory surgical
3 treatment center shall waive the costs charged to patients for
4 any follow-up surgery that results from a previous surgical
5 error that occurred at that ambulatory surgical treatment
6 center.

7 Section 910. The Hospital Licensing Act is amended by
8 adding Section 11.9 as follows:

9 (210 ILCS 85/11.9 new)

10 Sec. 11.9. Waiver of surgical costs. A hospital shall
11 wave the costs charged to patients for any follow-up surgery
12 that results from a previous surgical error that occurred at
13 that hospital.

14 Section 999. Effective date. This Act takes effect upon
15 becoming law.