7092

IN SENATE

April 25, 2014

Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law and the general business law, in relation to the warranting of medical devices

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

- 1 Section 1. Section 2803 of the public health law is amended by adding 2 a new subdivision 8-b to read as follows:
- 8-B. THE COMMISSIONER SHALL ESTABLISH PROCEDURES TO BE FOLLOWED BY HOSPITALS FOR NOTIFICATION TO PATIENTS WHO RECEIVE MEDICAL DEVICES DURING THE COURSE OF THEIR TREATMENT, THAT SUCH DEVICES ARE WARRANTED FOR A PERIOD OF SEVEN YEARS FOR ELECTRONIC MEDICAL DEVICES AND FOR A PERIOD OF TEN YEARS FOR ALL OTHER MEDICAL DEVICES, PURSUANT TO ARTICLE THIRTY-B OF THE GENERAL BUSINESS LAW.
- 9 S 2. The general business law is amended by adding a new article 30-B 10 to read as follows:

11 ARTICLE 30-B 12 MEDICAL DEVICE WARRANTY

13 SECTION 645. DEFINITIONS.

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- 646. EXPRESS WARRANTY REQUIRED.
- 647. ADDITIONAL REMEDIES OF CONSUMERS.
- 648. PROHIBITION AGAINST WAIVER OF RIGHTS.
- S 645. DEFINITIONS. WHENEVER USED IN THIS ARTICLE, UNLESS THE CONTEXT CLEARLY REQUIRES OTHERWISE, THE FOLLOWING WORDS OR TERMS SHALL HAVE THE FOLLOWING MEANINGS:
- 1. "CONSUMER" MEANS THE PERSON UPON WHICH A MEDICAL DEVICE WAS USED, ATTACHED OR APPLIED, REGARDLESS OF WHO PURCHASED OR ACQUIRED SUCH DEVICE.
- 23 2. "ELECTRONIC MEDICAL DEVICE" MEANS A MEDICAL DEVICE THAT REQUIRES A 24 BATTERY OR SIMILAR POWER SOURCE TO FUNCTION.
- 3. "MEDICAL DEVICE" MEANS INSTRUMENTS, APPARATUS AND CONTRIVANCES, INCLUDING THEIR PARTS, COMPONENTS AND ACCESSORIES INTENDED FOR THE CURE,

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [] is old law to be omitted.

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MITIGATION, TREATMENT OR PREVENTION OF ANY DISEASE, CONDITION OR INJURY 2 IN HUMANS.

- 3 4. "INITIAL SELLER" MEANS THE SELLER WHO MANUFACTURED, MODIFIED, REBUILT, IMPROVED OR RECONDITIONED A MEDICAL DEVICE.
 - S 646. EXPRESS WARRANTY REQUIRED. 1. EVERY INITIAL SELLER OF A MEDICAL DEVICE, OTHER THAN AN ELECTRONIC MEDICAL DEVICE, SHALL PROVIDE CONSUMER OF SUCH DEVICE WITH A WARRANTY THAT THE MEDICAL DEVICE IS FIT FOR THE ORDINARY PURPOSES FOR WHICH SUCH DEVICE IS USED, AND FROM DEFECTS FOR A PERIOD OF TEN YEARS AFTER THE MEDICAL DEVICE IS FIRST USED BY, ATTACHED TO OR APPLIED TO THE CONSUMER.
 - EVERY INITIAL SELLER OF AN ELECTRONIC MEDICAL DEVICE SHALL PROVIDE EACH CONSUMER OF SUCH DEVICE WITH A WARRANTY THAT THE ELECTRONIC MEDICAL DEVICE IS FIT FOR THE ORDINARY PURPOSES FOR WHICH SUCH DEVICE IS USED, AND IS FREE FROM DEFECTS FOR A PERIOD OF SEVEN YEARS AFTER THE ELECTRON-IC MEDICAL DEVICE IS FIRST USED BY, ATTACHED TO OR APPLIED TO THE CONSUMER.
 - 3. IF A MEDICAL DEVICE FAILS TO CONFORM TO THE WARRANTY REQUIRED BY SUBDIVISION ONE OR TWO OF THIS SECTION, AND THE CONSUMER, OR HIS OR HER AUTHORIZED REPRESENTATIVE REPORTS SUCH NONCONFORMITY OR DEFECT TO THE INITIAL SELLER OR ITS AGENTS DURING THE TERM OF THE WARRANTY, THE INITIAL SELLER SHALL BE LIABLE FOR ALL COSTS INCURRED BY THE CONSUMER OR HIS OR HER INSURER TO MAKE SUCH REPAIRS AND REPLACEMENTS AS ARE NECES-SARY TO CORRECT SUCH CONFORMITY OR DEFECT, AND ANY ADDITIONAL MEDICAL AND REHABILITATION CARE NECESSARY AFTER SUCH REPAIR OR REPLACEMENT.
- S 647. ADDITIONAL REMEDIES OF CONSUMERS. NOTHING IN THIS ARTICLE SHALL IN ANY WAY LIMIT THE RIGHTS, REMEDIES OR PRIVILEGES WHICH ARE 26 27 AVAILABLE TO A CONSUMER AT LAW OR EQUITY.
- 648. PROHIBITION AGAINST WAIVER OF RIGHTS. WAIVER OF ANY RIGHTS BY 28 THE CONSUMER UNDER THIS ARTICLE SHALL BE DEEMED CONTRARY TO PUBLIC POLI-29 CY AND SHALL BE UNENFORCEABLE AND VOID. 30
- S 3. This act shall take effect on the first of January next succeed-31 32 ing the date on which it shall have become a law, and shall apply to 33 medical devices initially used by, attached to or applied to a person on 34 or after such date.