S T A T E O F N E W Y O R K

5566--A

2015-2016 Regular Sessions

I N S E N A T E

May 14, 2015

Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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

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

Section 1. Section 2803 of the public health law is amended by adding 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 ELECTRONIC MEDICAL DEVICES OR IMPLANTABLE HIP OR KNEE MEDICAL DEVICES, AS DEFINED IN ARTICLE THIRTY-B OF THE GENERAL BUSINESS LAW, DURING THE COURSE OF THEIR TREATMENT, THAT SUCH DEVICES ARE WARRANTED FOR A PERIOD OF AT LEAST FIVE YEARS.

S 2. The general business law is amended by adding a new article 30-B to read as follows:

ARTICLE 30-B

MEDICAL DEVICE WARRANTY

SECTION 645. DEFINITIONS.
646. EXPRESS WARRANTY REQUIRED.
647. ADDITIONAL REMEDIES OF CONSUMERS.
648. PROHIBITION AGAINST WAIVER OF RIGHTS.
649. EXCLUSION.

S 645. DEFINITIONS. WHENEVER USED IN THIS ARTICLE, UNLESS THE CONTEXT CLEARLY REQUIRES OTHERWISE, THE FOLLOWING WORDS OR TERMS SHALL HAVE THE FOLLOWING MEANINGS:

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

LBD00303-04-6

1. "CONSUMER" MEANS THE PERSON UPON WHICH A MEDICAL DEVICE WAS USED, ATTACHED OR APPLIED, REGARDLESS OF WHO PURCHASED OR ACQUIRED SUCH DEVICE.

2. "ELECTRONIC MEDICAL DEVICE" MEANS AN IMPLANTABLE MEDICAL DEVICE THAT REQUIRES A BATTERY OR SIMILAR POWER SOURCE TO FUNCTION.

3. "IMPLANTABLE HIP OR KNEE MEDICAL DEVICE" MEANS A DEVICE THAT REPLACES THE COMPONENTS OF A HIP OR KNEE.

4. "INITIAL SELLER" MEANS THE SELLER WHO MANUFACTURED, MODIFIED, REBUILT, IMPROVED OR RECONDITIONED AN IMPLANTABLE ELECTRONIC OR HIP OR KNEE MEDICAL DEVICE.

S 646. EXPRESS WARRANTY REQUIRED. 1. EVERY INITIAL SELLER OF AN ELECTRONIC MEDICAL DEVICE OR IMPLANTABLE HIP OR KNEE MEDICAL DEVICE SHALL PROVIDE EACH CONSUMER OF SUCH DEVICE WITH A WARRANTY THAT THE MEDICAL DEVICE IS FIT FOR THE ORDINARY PURPOSES FOR WHICH SUCH DEVICE IS USED, AND IS FREE FROM DEFECTS FOR A PERIOD OF AT LEAST FIVE YEARS AFTER THE MEDICAL DEVICE IS FIRST USED BY, ATTACHED TO OR APPLIED TO THE CONSUMER.

2. IF A MEDICAL DEVICE FAILS TO CONFORM TO THE WARRANTY REQUIRED BY SUBDIVISION ONE 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 NECESSARY 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 OTHERWISE AVAILABLE TO A CONSUMER AT LAW OR EQUITY.

S 648. PROHIBITION AGAINST WAIVER OF RIGHTS. WAIVER OF ANY RIGHTS BY THE CONSUMER UNDER THIS ARTICLE SHALL BE DEEMED CONTRARY TO PUBLIC POLICY AND SHALL BE UNENFORCEABLE AND VOID.

S 649. EXCLUSION. THE PROVISIONS OF THIS ARTICLE SHALL NOT APPLY TO DEVICES APPROVED THROUGH THE UNITED STATES FOOD AND DRUG ADMINISTRATION PRE-MARKET APPROVAL PROCESS WHERE 21 USC 360(K) WOULD PROHIBIT IMPOSITION OF THE WARRANTY ESTABLISHED UNDER THIS ARTICLE.

S 3. This act shall take effect on the first of January next succeeding the date on which it shall have become a law, and shall apply to medical devices initially used by, attached to or applied to a person on or after such date.