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H. R. 1016

To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to adopt and implement a standard identification protocol for use in the tracking and procurement of biological implants by the Department of Veterans Affairs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 20, 2015

Mr. ROE of Tennessee introduced the following bill; which was referred to the Committee on Veterans' Affairs

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A BILL

To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to adopt and implement a standard identification protocol for use in the tracking and procurement of biological implants by the Department of Veterans Affairs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Biological Implant Tracking and Veteran Safety Act of 2015".

SEC. 2. IDENTIFICATION AND TRACKING OF BIOLOGICAL IMPLANTS USED IN DEPARTMENT OF VETERANS AFFAIRS MEDICAL FACILITIES.

(a) IN GENERAL.—Subchapter II of chapter 73 of title 38, United States Code, is amended by adding at the end the following new section:

"§ 7330B. Identification and tracking of biological implants

"(a) STANDARD IDENTIFICATION SYSTEM FOR BIOLOGICAL IMPLANTS.—(1) The Secretary shall adopt the unique device identification system developed for medical devices by the Food and Drug Administration pursuant to section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)), or implement a comparable standard identification system, for use in identifying biological implants intended for use in medical procedures conducted in medical facilities of the Department.

"(2) In adopting or implementing a standard identification system for biological implants under paragraph (1), the Secretary shall permit a vendor to use any of the accredited entities identified by the Food and Drug Administration as an issuing agency pursuant to section 830.100 of title 21, Code of Federal Regulations, or any successor regulation.

"(b) BIOLOGICAL IMPLANT TRACKING SYSTEM.—(1) The Secretary shall implement a system for tracking the

1 biological implants referred to in subsection (a) from
2 human donor or animal source to implantation. Such sys-
3 tem shall be compatible with the identification system
4 adopted or implemented under subsection (a).

5 "(2) The Secretary shall implement inventory con-
6 trols compatible with the tracking system implemented
7 under paragraph (1) so that all patients who have re-
8 ceived, in a medical facility of the Department, a biological
9 implant subject to a recall can be notified of the recall,
10 if based on the evaluation of appropriate medical per-
11 sonnel of the Department of the risks and benefits, the
12 Secretary determines such notification is appropriate.

13 "(c) CONSISTENCY WITH FOOD AND DRUG ADMINIS-
14 TRATION REGULATIONS.—To the extent that a conflict
15 arises between this section and a provision of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
17 or sections 351 or 361 of the Public Health Service Act
18 (42 U.S.C. 262) (including any regulations issued under
19 such Acts), the provision the Federal Food, Drug, and
20 Cosmetic Act or Public Health Service Act (including any
21 regulations issued under such Acts) shall apply.

22 "(d) DEFINITION OF BIOLOGICAL IMPLANT.—In this
23 section, the term 'biological implant' means any animal
24 or human cell, tissue, or cellular or tissue-based product—

"(1) under the meaning given the term 'human cells' in section 1271.3 of title 21, Code of Federal Regulations, or any successor regulation; or

"(2) that is regulated as a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act.".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by adding at the end of the items relating to such subchapter the following new item:

"7330B. Identification and tracking of biological implants.".

(c) IMPLEMENTATION DEADLINES.—

(1) STANDARD IDENTIFICATION SYSTEM.—

(A) IN GENERAL.—With respect to biological implants described in paragraph (1) of subsection (d) of section 7330B of title 38, United States Code, as added by subsection (a), the Secretary of Veterans Affairs shall adopt or implement a standard identification system for biological implants, as required by subsection (a) of such section, by not later than the date that is 180 days after the date of the enactment of this Act.

(B) IMPLANTS REGULATED AS DEVICES.—With respect to biological implants described in paragraph (2) of subsection (d) of such section,

the Secretary of Veterans Affairs shall adopt or implement such standard identification system in compliance with the compliance dates established by the Food and Drug Administration pursuant to section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)).

(2) TRACKING SYSTEM.—The Secretary of Veterans Affairs shall implement the biological implant tracking system required by subsection (b) of section 7330B, as added by subsection (a), by not later than the date that is 180 days after the date of the enactment of this Act.

(d) REPORTING REQUIREMENT.—If the biological implant tracking system required by subsection (b) of such section is not operational by the date that is 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall provide to the Committees on Veterans' Affairs of the Senate and House of Representatives a written explanation for each month until such time as the system is operational. Each such explanation shall describe each impediment to the implementation of the system, steps being taken to remediate each such impediment, and target dates for a solution to each such impediment.

SEC. 3. PROCUREMENT OF BIOLOGICAL IMPLANTS USED IN DEPARTMENT OF VETERANS AFFAIRS MEDICAL FACILITIES.

(a) PROCUREMENT.—

(1) IN GENERAL.—Subchapter II of chapter 81 of such title is amended by adding at the end the following new section:

"§ 8129. Procurement of biological implants

''(a) IN GENERAL.—(1) The Secretary may procure biological implants of human origin only from vendors that meet the following conditions:

''(A) The vendor uses the standard identification system adopted or implemented by the Secretary under section 7330B(a) of this title and has safeguards to ensure that a production identifier has been in place at each step of distribution of each biological implant from its donor.

''(B) The vendor is registered as required by the Food and Drug Administration under subpart B of part 1271 of title 21, Code of Federal Regulations, or any successor regulation, and in the case of a vendor that uses a tissue distribution intermediary or a tissue processor, the vendor provides assurances that the tissue distribution intermediary or tissue processor is registered as required by the Food and Drug Administration.

"(C) The vendor ensures that donor eligibility determinations and such other records as the Secretary may require accompany each biological implant at all times, regardless of the country of origin of the donor of the biological material.

"(D) The vendor consents to periodic inspections and audits by the Secretary regarding the accuracy of records and the handling of products.

"(E) The vendor agrees to cooperate with all biological implant recalls conducted on the vendor's own initiative, on the initiative of the original product manufacturer used by the vendor, by the request of the Food and Drug Administration, or by a statutory order of the Food and Drug Administration.

"(F) The vendor agrees to notify the Secretary of any adverse event or reaction report it provides to the Food and Drug Administration, as required by section 1271.3 of title 21, Code of Federal Regulations, or any successor regulation, or of any warning letter from the Food and Drug Administration issued to the vendor or a tissue processor or tissue distribution intermediary it uses by not later than 60 days after the vendor receives such report or warning letter.

"(G) The vendor agrees to retain all records associated with the procurement of a biological implant by the Department for at least five years after the date of the procurement of the biological implant.

"(H) The vendor provides assurances that the biological implants provided by the vendor are acquired only from tissue processors that maintain active accreditation with the American Association of Tissue Banks or a similar national accreditation specific to biological implants.

"(2) The Secretary may procure biological implants of non-human origin only from vendors that meet the following conditions:

"(A) The vendor uses the standard identification system adopted or implemented by the Secretary under section 7330B(a) of this title.

"(B) The vendor is registered as required by the Food and Drug Administration under section 807.3(c) of title 21, Code of Federal Regulations, or any successor regulation, and in the case of a vendor that is not the original product manufacturer of such implants the vendor provides assurances that the original product manufacturer is registered as required by the Food and Drug Administration.

"(C) The vendor consents to periodic inspections and audits by the Secretary regarding the accuracy of records and the handling of products.

"(D) The vendor agrees to cooperate with all biological implant recalls conducted on the vendor's own initiative, on the initiative of the original product manufacturer used by the vendor, by the request of the Food and Drug Administration, or by a statutory order of the Food and Drug Administration.

"(E) The vendor agrees to notify the Secretary of any adverse event report it provides to the Food and Drug Administration as required in 21 C.F.R. part 803 or any warning letter from the Food and Drug Administration issued to the vendor or the original product manufacturer it uses by not later than 60 days after the vendor receives such report or warning letter.

"(F) The vendor agrees to retain all records associated with the procurement of a biological implant by the Department for at least five years after the date of the procurement of the biological implant.

"(3) The Secretary shall procure biological implants under the Federal Supply Schedules of the General Services Administration, unless such implants are not available under such Schedules. For biological implants listed on

the Federal Supply Schedules, the Secretary shall accommodate reasonable vendor requests to undertake outreach efforts to educate medical professionals of the Department about the use and efficacy of such biological implants.

"(4) Section 8123 of this title shall not apply to the procurement of biological implants.

"(5) In the case of biological implants that are unavailable for procurement under the Federal Supply Schedules, the Secretary shall procure such implants using competitive procedures in accordance with applicable law and the Federal Acquisition Regulation.

"(b) PENALTIES.—In addition to any applicable penalty under any other provision of law, any procurement employee of the Department who is found responsible for a biological implant procurement transaction with intent to avoid or with reckless disregard of the requirements of this section shall be ineligible to hold a certificate of appointment as a contracting officer or to serve as the representative of an ordering officer, contracting officer, or purchase card holder.

"(c) DEFINITIONS.—In this section:

"(1) The term 'biological implant' shall have the meaning given such term in section 7330B(d) of this title.

"(2) The term 'production identifier' means a distinct identification code that—

"(A) relates a biological implant to the human donor of the implant and to all records pertaining to the implant;

"(B) includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor; and

"(C) satisfies the requirements of subsection (c) of section 1271.290 of title 21, Code of Federal Regulations, or any successor regulation.

"(3) The term 'tissue distribution intermediary' means an agency that acquires and stores human tissue for further distribution and performs no other tissue banking functions.

"(4) The term 'tissue processor' means an entity processing human tissue for use in biological implants including activities performed on tissue other than donor screening, donor testing, tissue recovery and collection functions, storage, or distribution.".

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended

by adding at the end of the items relating to such subchapter the following new item:

"8129. Procurement of biological implants.".

(b) EFFECTIVE DATE.—Section 8129 of title 38, United States Code, as added by subsection (a), shall take effect on the date that is 180 days after the date on which the tracking system required under subsection (b) of section 7330B of such title, as added by section 2(a) is implemented.

(c) SPECIAL RULE FOR CRYOPRESERVED PRODUCTS.—During the three-year period beginning on the effective date of section 8129 of title 38, United States Code, as added by subsection (a), biological implants produced and labeled before that date may be procured by the Department of Veterans Affairs without relabeling under the standard identification system adopted or implemented under section 7330B of such title, as added by section 2(a).

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