I

116TH CONGRESS
1ST SESSION

H. R. 547

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

JANUARY 15, 2019

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

---

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 2019".

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:

"§ 7330D. 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 under 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

biological implants described in subsection (a) from human donor or animal source to implantation.

''(2) The tracking system implemented under paragraph (1) shall be compatible with the identification system adopted or implemented under subsection (a).

''(3) The Secretary shall implement inventory controls compatible with the tracking system implemented under paragraph (1) so that all patients who have received, in a medical facility of the Department, a biological implant subject to a recall can be notified of the recall if, based on the evaluation by appropriate medical personnel of the Department of the risks and benefits, the Secretary determines such notification is appropriate.

''(c) CONSISTENCY WITH FOOD AND DRUG ADMINISTRATION REGULATIONS.—To the extent that a conflict arises between this section and a provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 or 361 of the Public Health Service Act (42 U.S.C. 262 and 264) (including any regulations issued under such provisions), the provision of the Federal Food, Drug, and Cosmetic Act or Public Health Service Act (including any regulations issued under such provisions) shall apply.

''(d) BIOLOGICAL IMPLANT DEFINED.—In this section, the term 'biological implant' means any human cell,

tissue, or cellular or tissue-based product or animal product—

''(1) under the meaning given the term 'human cells, tissues, or cellular or tissue-based products' 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 (21 U.S.C. 321(h)).''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 7330C the following new item:

''7330D. Identification and tracking of biological implants.''.

(c) IMPLEMENTATION DEADLINES.—

(1) STANDARD IDENTIFICATION SYSTEM.—The Secretary of Veterans Affairs shall adopt or implement the standard identification system for biological implants required by subsection (a) of section 7330C of title 38, United States Code, as added by subsection (a), with respect to biological implants described in—

(A) subsection (d)(1) of such section, by not later than the date that is 180 days after the date of the enactment of this Act; and

(B) subsection (d)(2) of such section, in compliance with the compliance dates established by the Food and Drug Administration under 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 section 7330C(b) of title 38, United States Code, 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.—

(1) IN GENERAL.—If the biological implant tracking system required by section 7330C(b) of title 38, United States Code, as added by subsection (a), 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 submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report explaining why the system is not operational for each month until such time as the system is operational.

(2) ELEMENTS.—Each report submitted under paragraph (1) shall include a description of the following:

(A) Each impediment to the implementation of the system described in such paragraph.

(B) Steps being taken to remediate each such impediment.

(C) 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 title 38, United States Code, 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 7330C(a) of this title and has safeguards to ensure that a distinct 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 agrees to cooperate with all biological implant recalls conducted on the initiative of the vendor, 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 or reaction report it provides to the Food and Drug Administration, as required

by sections 1271.3 and 1271.350 of title 21, Code of Federal Regulations, or any successor regulation, or any warning letter from the Food and Drug Administration issued to the vendor or a tissue processor or tissue distribution intermediary used by the vendor 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 10 years after the date of the procurement of the biological implant.

''(G) 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 nonhuman 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 7330C(a) of this title.

''(B) The vendor is registered as an establishment as required by the Food and Drug Administra-

tion under sections 807.20 and 807.40 of title 21, Code of Federal Regulations, or any successor regulation (or is not required to register pursuant to section 807.65(a) of such title, 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 (or is not required to register).

''(C) The vendor agrees to cooperate with all biological implant recalls conducted on the initiative of the vendor, 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.

''(D) The vendor agrees to notify the Secretary of any adverse event report it provides to the Food and Drug Administration as required under part 803 of title 21, Code of Federal Regulations, or any successor regulation, or any warning letter from the Food and Drug Administration issued to the vendor or the original product manufacturer used by the vendor by not later than 60 days after the vendor receives such report or warning letter.

''(E) The vendor agrees to retain all records associated with the procurement of a biological implant by the Department for at least 10 years after the date of the procurement of the biological implant.

''(3)(A) 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.

''(B) With respect to 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.

''(C) 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, including through the use of a national contract.

''(4) In procuring biological implants under this section, 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.

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

''(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' has the meaning given that term in section 7330C(d) of this title.

''(2) The term 'distinct 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 section 1271.290(c) 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 chapter 81 is amended by inserting after the item relating to section 8128 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 section 7330C(b) 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 pro-

duced and labeled before that effective date may be procured by the Department of Veterans Affairs without relabeling under the standard identification system adopted or implemented under section 7330C of such title, as added by section 2(a).

SEC. 4. FUNDING.

No additional funds are authorized to carry out the requirements of this Act and the amendments made by this Act. Such requirements shall be carried out using amounts otherwise authorized.

○