

114TH CONGRESS
1ST SESSION

S. 2334

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 SENATE OF THE UNITED STATES

NOVEMBER 30, 2015

Mr. CASSIDY introduced the following bill; which was read twice and 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Biological Implant
5 Tracking and Veteran Safety Act of 2015”.

1 **SEC. 2. IDENTIFICATION AND TRACKING OF BIOLOGICAL**
2 **IMPLANTS USED IN DEPARTMENT OF VET-**
3 **ERANS AFFAIRS MEDICAL FACILITIES.**

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

7 **“§ 7330B. Identification and tracking of biological im-**
8 **plants**

9 “(a) STANDARD IDENTIFICATION SYSTEM FOR BIO-
10 LOGICAL IMPLANTS.—(1) The Secretary shall adopt the
11 unique device identification system developed for medical
12 devices by the Food and Drug Administration under sec-
13 tion 519(f) of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 360i(f)), or implement a comparable standard
15 identification system, for use in identifying biological im-
16 plants intended for use in medical procedures conducted
17 in medical facilities of the Department.

18 “(2) In adopting or implementing a standard identi-
19 fication system for biological implants under paragraph
20 (1), the Secretary shall permit a vendor to use any of the
21 accredited entities identified by the Food and Drug Ad-
22 ministration as an issuing agency pursuant to section
23 830.100 of title 21, Code of Federal Regulations, or any
24 successor regulation.

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

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

3 “(2) The tracking system implemented under para-
4 graph (1) shall be compatible with the identification sys-
5 tem adopted or implemented under subsection (a).

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

14 “(c) CONSISTENCY WITH FOOD AND DRUG ADMINIS-
15 TRATION REGULATIONS.—To the extent that a conflict
16 arises between this section and a provision of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
18 or sections 351 or 361 of the Public Health Service Act
19 (42 U.S.C. 262 and 264) (including any regulations issued
20 under such provisions), the provision of the Federal Food,
21 Drug, and Cosmetic Act or Public Health Service Act (in-
22 cluding any regulations issued under such provisions) shall
23 apply.

24 “(d) BIOLOGICAL IMPLANT DEFINED.—In this sec-
25 tion, the term ‘biological implant’ means any human cell,

1 tissue, or cellular or tissue-based product or animal prod-
 2 uct—

3 “(1) under the meaning given the term ‘human
 4 cells, tissues, or cellular or tissue-based products’ in
 5 section 1271.3 of title 21, Code of Federal Regula-
 6 tions, or any successor regulation; or

7 “(2) that is regulated as a device under section
 8 201(h) of the Federal Food, Drug, and Cosmetic
 9 Act (21 U.S.C. 321(h)).”.

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

“7330B. Identification and tracking of biological implants.”.

14 (c) IMPLEMENTATION DEADLINES.—

15 (1) STANDARD IDENTIFICATION SYSTEM.—The
 16 Secretary of Veterans Affairs shall adopt or imple-
 17 ment the standard identification system for biologi-
 18 cal implants required by subsection (a) of section
 19 7330B of title 38, United States Code, as added by
 20 subsection (a), with respect to biological implants
 21 described in—

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

1 (B) subsection (d)(2) of such section, in
2 compliance with the compliance dates estab-
3 lished by the Food and Drug Administration
4 under section 519(f) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 360i(f)).

6 (2) TRACKING SYSTEM.—The Secretary of Vet-
7 erans Affairs shall implement the biological implant
8 tracking system required by section 7330B(b) of
9 title 38, United States Code, as added by subsection
10 (a), by not later than the date that is 180 days after
11 the date of the enactment of this Act.

12 (d) REPORTING REQUIREMENT.—

13 (1) IN GENERAL.—If the biological implant
14 tracking system required by section 7330B(b) of
15 title 38, United States Code, as added by subsection
16 (a), is not operational by the date that is 180 days
17 after the date of the enactment of this Act, the Sec-
18 retary of Veterans Affairs shall submit to the Com-
19 mittee on Veterans' Affairs of the Senate and the
20 Committee on Veterans' Affairs of the House of
21 Representatives a written explanation on why the
22 system is not operational for each month until such
23 time as the system is operational.

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

4 (A) Each impediment to the implementa-
 5 tion of the system described in such paragraph.

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

8 (C) Target dates for a solution to each
 9 such impediment.

10 **SEC. 3. PROCUREMENT OF BIOLOGICAL IMPLANTS USED IN**
 11 **DEPARTMENT OF VETERANS AFFAIRS MED-**
 12 **ICAL FACILITIES.**

13 (a) PROCUREMENT.—

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

17 **“§ 8129. Procurement of biological implants**

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

21 “(A) The vendor uses the standard identifica-
 22 tion system adopted or implemented by the Sec-
 23 retary under section 7330B(a) of this title and has
 24 safeguards to ensure that a distinct identifier has

1 been in place at each step of distribution of each bio-
2 logical implant from its donor.

3 “(B) The vendor is registered as required by
4 the Food and Drug Administration under subpart B
5 of part 1271 of title 21, Code of Federal Regula-
6 tions, or any successor regulation, and in the case of
7 a vendor that uses a tissue distribution intermediary
8 or a tissue processor, the vendor provides assurances
9 that the tissue distribution intermediary or tissue
10 processor is registered as required by the Food and
11 Drug Administration.

12 “(C) The vendor ensures that donor eligibility
13 determinations and such other records as the Sec-
14 retary may require accompany each biological im-
15 plant at all times, regardless of the country of origin
16 of the donor of the biological material.

17 “(D) The vendor agrees to cooperate with all
18 biological implant recalls conducted on the initiative
19 of the vendor, on the initiative of the original prod-
20 uct manufacturer used by the vendor, by the request
21 of the Food and Drug Administration, or by a statu-
22 tory order of the Food and Drug Administration.

23 “(E) The vendor agrees to notify the Secretary
24 of any adverse event or reaction report it provides
25 to the Food and Drug Administration, as required

1 by sections 1271.3 and 1271.350 of title 21, Code
2 of Federal Regulations, or any successor regulation,
3 or any warning letter from the Food and Drug Ad-
4 ministration issued to the vendor or a tissue proc-
5 essor or tissue distribution intermediary used by the
6 vendor by not later than 60 days after the vendor
7 receives such report or warning letter.

8 “(F) The vendor agrees to retain all records as-
9 sociated with the procurement of a biological implant
10 by the Department for at least 10 years after the
11 date of the procurement of the biological implant.

12 “(G) The vendor provides assurances that the
13 biological implants provided by the vendor are ac-
14 quired only from tissue processors that maintain ac-
15 tive accreditation with the American Association of
16 Tissue Banks or a similar national accreditation spe-
17 cific to biological implants.

18 “(2) The Secretary may procure biological implants
19 of non-human origin only from vendors that meet the fol-
20 lowing conditions:

21 “(A) The vendor uses the standard identifica-
22 tion system adopted or implemented by the Sec-
23 retary under section 7330B(a) of this title.

24 “(B) The vendor is registered as an establish-
25 ment as required by the Food and Drug Administra-

1 tion under sections 807.20 and 807.40 of title 21,
2 Code of Federal Regulations, or any successor regu-
3 lation (or is not required to register pursuant to sec-
4 tion 807.65(a) of such title, or any successor regula-
5 tion), and in the case of a vendor that is not the
6 original product manufacturer of such implants, the
7 vendor provides assurances that the original product
8 manufacturer is registered as required by the Food
9 and Drug Administration (or is not required to reg-
10 ister).

11 “(C) The vendor agrees to cooperate with all bi-
12 ological implant recalls conducted on the initiative of
13 the vendor, on the initiative of the original product
14 manufacturer used by the vendor, by the request of
15 the Food and Drug Administration, or by a statu-
16 tory order of the Food and Drug Administration.

17 “(D) The vendor agrees to notify the Secretary
18 of any adverse event report it provides to the Food
19 and Drug Administration as required under part
20 803 of title 21, Code of Federal Regulations, or any
21 successor regulation, or any warning letter from the
22 Food and Drug Administration issued to the vendor
23 or the original product manufacturer used by the
24 vendor by not later than 60 days after the vendor
25 receives such report or warning letter.

1 “(E) The vendor agrees to retain all records as-
2 sociated with the procurement of a biological implant
3 by the Department for at least 10 years after the
4 date of the procurement of the biological implant.

5 “(3)(A) The Secretary shall procure biological im-
6 plants under the Federal Supply Schedules of the General
7 Services Administration unless such implants are not
8 available under such Schedules.

9 “(B) With respect to biological implants listed on the
10 Federal Supply Schedules, the Secretary shall accommo-
11 date reasonable vendor requests to undertake outreach ef-
12 forts to educate medical professionals of the Department
13 about the use and efficacy of such biological implants.

14 “(C) In the case of biological implants that are un-
15 available for procurement under the Federal Supply
16 Schedules, the Secretary shall procure such implants using
17 competitive procedures in accordance with applicable law
18 and the Federal Acquisition Regulation.

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

21 “(b) PENALTIES.—In addition to any applicable pen-
22 alty under any other provision of law, any procurement
23 employee of the Department who is found responsible for
24 a biological implant procurement transaction with intent
25 to avoid or with reckless disregard of the requirements of

1 this section shall be ineligible to hold a certificate of ap-
2 pointment as a contracting officer or to serve as the rep-
3 resentative of an ordering officer, contracting officer, or
4 purchase card holder.

5 “(c) DEFINITIONS.—In this section:

6 “(1) The term ‘biological implant’ has the
7 meaning given such term in section 7330B(d) of this
8 title.

9 “(2) The term ‘distinct identifier’ means a dis-
10 tinct identification code that—

11 “(A) relates a biological implant to the
12 human donor of the implant and to all records
13 pertaining to the implant;

14 “(B) includes information designed to fa-
15 cilitate effective tracking, using the distinct
16 identification code, from the donor to the recipi-
17 ent and from the recipient to the donor; and

18 “(C) satisfies the requirements of section
19 1271.290(c) of title 21, Code of Federal Regu-
20 lations, or any successor regulation.

21 “(3) The term ‘tissue distribution intermediary’
22 means an agency that acquires and stores human
23 tissue for further distribution and performs no other
24 tissue banking functions.

1 “(4) The term ‘tissue processor’ means an enti-
 2 ty processing human tissue for use in biological im-
 3 plants, including activities performed on tissue other
 4 than donor screening, donor testing, tissue recovery
 5 and collection functions, storage, or distribution.”.

6 (2) CLERICAL AMENDMENT.—The table of sec-
 7 tions at the beginning of such chapter is amended
 8 by inserting after the item relating to section 8128
 9 the following new item:

“8129. Procurement of biological implants.”.

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

15 (c) SPECIAL RULE FOR CRYOPRESERVED PROD-
 16 UCTS.—During the three-year period beginning on the ef-
 17 fective date of section 8129 of title 38, United States
 18 Code, as added by subsection (a), biological implants pro-
 19 duced and labeled before that effective date may be pro-
 20 cured by the Department of Veterans Affairs without re-
 21 labeling under the standard identification system adopted
 22 or implemented under section 7330B of such title, as
 23 added by section 2(a).

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