

114TH CONGRESS
1ST SESSION

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

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 pursuant
13 to section 519(f) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 360i(f)), or implement a comparable
15 standard identification system, for use in identifying bio-
16 logical implants intended for use in medical procedures
17 conducted 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 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 “(1) under the meaning given the term ‘human
2 cells’ in section 1271.3 of title 21, Code of Federal
3 Regulations, or any successor regulation; or

4 “(2) that is regulated as a device under section
5 201(h) of the Federal Food, Drug, and Cosmetic
6 Act.”.

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

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

11 (c) IMPLEMENTATION DEADLINES.—

12 (1) STANDARD IDENTIFICATION SYSTEM.—

13 (A) IN GENERAL.—With respect to biologi-
14 cal implants described in paragraph (1) of sub-
15 section (d) of section 7330B of title 38, United
16 States Code, as added by subsection (a), the
17 Secretary of Veterans Affairs shall adopt or im-
18 plement a standard identification system for bi-
19 ological implants, as required by subsection (a)
20 of such section, by not later than the date that
21 is 180 days after the date of the enactment of
22 this Act.

23 (B) IMPLANTS REGULATED AS DEVICES.—

24 With respect to biological implants described in
25 paragraph (2) of subsection (d) of such section,

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

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

13 (d) REPORTING REQUIREMENT.—If the biological
14 implant tracking system required by subsection (b) of such
15 section is not operational by the date that is 180 days
16 after the date of the enactment of this Act, the Secretary
17 of Veterans Affairs shall provide to the Committees on
18 Veterans' Affairs of the Senate and House of Representa-
19 tives a written explanation for each month until such time
20 as the system is operational. Each such explanation shall
21 describe each impediment to the implementation of the
22 system, steps being taken to remediate each such impedi-
23 ment, and target dates for a solution to each such impedi-
24 ment.

1 **SEC. 3. PROCUREMENT OF BIOLOGICAL IMPLANTS USED IN**
2 **DEPARTMENT OF VETERANS AFFAIRS MED-**
3 **ICAL FACILITIES.**

4 (a) PROCUREMENT.—

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

8 **“§ 8129. Procurement of biological implants**

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

12 “(A) The vendor uses the standard identifica-
13 tion system adopted or implemented by the Sec-
14 retary under section 7330B(a) of this title and has
15 safeguards to ensure that a production identifier has
16 been in place at each step of distribution of each bio-
17 logical implant from its donor.

18 “(B) The vendor is registered as required by
19 the Food and Drug Administration under subpart B
20 of part 1271 of title 21, Code of Federal Regula-
21 tions, or any successor regulation, and in the case of
22 a vendor that uses a tissue distribution intermediary
23 or a tissue processor, the vendor provides assurances
24 that the tissue distribution intermediary or tissue
25 processor is registered as required by the Food and
26 Drug Administration.

1 “(C) The vendor ensures that donor eligibility
2 determinations and such other records as the Sec-
3 retary may require accompany each biological im-
4 plant at all times, regardless of the country of origin
5 of the donor of the biological material.

6 “(D) The vendor consents to periodic inspec-
7 tions and audits by the Secretary regarding the ac-
8 curacy of records and the handling of products.

9 “(E) The vendor agrees to cooperate with all bi-
10 ological implant recalls conducted on the vendor’s
11 own initiative, on the initiative of the original prod-
12 uct manufacturer used by the vendor, by the request
13 of the Food and Drug Administration, or by a statu-
14 tory order of the Food and Drug Administration.

15 “(F) The vendor agrees to notify the Secretary
16 of any adverse event or reaction report it provides
17 to the Food and Drug Administration, as required
18 by section 1271.3 of title 21, Code of Federal Regu-
19 lations, or any successor regulation, or of any warn-
20 ing letter from the Food and Drug Administration
21 issued to the vendor or a tissue processor or tissue
22 distribution intermediary it uses by not later than
23 60 days after the vendor receives such report or
24 warning letter.

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

5 “(H) The vendor provides assurances that the
6 biological implants provided by the vendor are ac-
7 quired only from tissue processors that maintain ac-
8 tive accreditation with the American Association of
9 Tissue Banks or a similar national accreditation spe-
10 cific to biological implants.

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

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

17 “(B) The vendor is registered as required by
18 the Food and Drug Administration under section
19 807.3(c) of title 21, Code of Federal Regulations, or
20 any successor regulation, and in the case of a vendor
21 that is not the original product manufacturer of
22 such implants the vendor provides assurances that
23 the original product manufacturer is registered as
24 required by the Food and Drug Administration.

1 “(C) The vendor consents to periodic inspec-
2 tions and audits by the Secretary regarding the ac-
3 curacy of records and the handling of products.

4 “(D) The vendor agrees to cooperate with all
5 biological implant recalls conducted on the vendor’s
6 own initiative, on the initiative of the original prod-
7 uct manufacturer used by the vendor, by the request
8 of the Food and Drug Administration, or by a statu-
9 tory order of the Food and Drug Administration.

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

18 “(F) The vendor agrees to retain all records as-
19 sociated with the procurement of a biological implant
20 by the Department for at least five years after the
21 date of the procurement of the biological implant.

22 “(3) The Secretary shall procure biological implants
23 under the Federal Supply Schedules of the General Serv-
24 ices Administration, unless such implants are not available
25 under such Schedules. For biological implants listed on

1 the Federal Supply Schedules, the Secretary shall accom-
2 modate reasonable vendor requests to undertake outreach
3 efforts to educate medical professionals of the Department
4 about the use and efficacy of such biological implants.

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

7 “(5) In the case of biological implants that are un-
8 available for procurement under the Federal Supply
9 Schedules, the Secretary shall procure such implants using
10 competitive procedures in accordance with applicable law
11 and the Federal Acquisition Regulation.

12 “(b) PENALTIES.—In addition to any applicable pen-
13 alty under any other provision of law, any procurement
14 employee of the Department who is found responsible for
15 a biological implant procurement transaction with intent
16 to avoid or with reckless disregard of the requirements of
17 this section shall be ineligible to hold a certificate of ap-
18 pointment as a contracting officer or to serve as the rep-
19 resentative of an ordering officer, contracting officer, or
20 purchase card holder.

21 “(c) DEFINITIONS.—In this section:

22 “(1) The term ‘biological implant’ shall have
23 the meaning given such term in section 7330B(d) of
24 this title.

1 “(2) The term ‘production identifier’ means a
2 distinct identification code that—

3 “(A) relates a biological implant to the
4 human donor of the implant and to all records
5 pertaining to the implant;

6 “(B) includes information designed to fa-
7 cilitate effective tracking, using the distinct
8 identification code, from the donor to the recipi-
9 ent and from the recipient to the donor; and

10 “(C) satisfies the requirements of sub-
11 section (c) of section 1271.290 of title 21, Code
12 of Federal Regulations, or any successor regula-
13 tion.

14 “(3) The term ‘tissue distribution intermediary’
15 means an agency that acquires and stores human
16 tissue for further distribution and performs no other
17 tissue banking functions.

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

23 (2) CLERICAL AMENDMENT.—The table of sec-
24 tions at the beginning of such chapter is amended

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

“8129. Procurement of biological implants.”.

3 (b) EFFECTIVE DATE.—Section 8129 of title 38,
4 United States Code, as added by subsection (a), shall take
5 effect on the date that is 180 days after the date on which
6 the tracking system required under subsection (b) of sec-
7 tion 7330B of such title, as added by section 2(a) is imple-
8 mented.

9 (c) SPECIAL RULE FOR CRYOPRESERVED PROD-
10 UCTS.—During the three-year period beginning on the ef-
11 fective date of section 8129 of title 38, United States
12 Code, as added by subsection (a), biological implants pro-
13 duced and labeled before that date may be procured by
14 the Department of Veterans Affairs without relabeling
15 under the standard identification system adopted or imple-
16 mented under section 7330B of such title, as added by
17 section 2(a).

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