

115TH CONGRESS  
1ST SESSION

# H. R. 28

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IN THE SENATE OF THE UNITED STATES

JANUARY 4, 2017

Received; read twice and referred to the Committee on Veterans' Affairs

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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Biological Implant  
3 Tracking and Veteran Safety Act of 2017”.

4 **SEC. 2. IDENTIFICATION AND TRACKING OF BIOLOGICAL**  
5 **IMPLANTS USED IN DEPARTMENT OF VET-**  
6 **ERANS AFFAIRS MEDICAL FACILITIES.**

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

10 **“§ 7330C. Identification and tracking of biological im-**  
11 **plants**

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

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

1 830.100 of title 21, Code of Federal Regulations, or any  
2 successor regulation.

3 “(b) BIOLOGICAL IMPLANT TRACKING SYSTEM.—(1)  
4 The Secretary shall implement a system for tracking the  
5 biological implants described in subsection (a) from  
6 human donor or animal source to implantation.

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

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

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

1 cluding any regulations issued under such provisions) shall  
2 apply.

3 “(d) BIOLOGICAL IMPLANT DEFINED.—In this sec-  
4 tion, the term ‘biological implant’ means any human cell,  
5 tissue, or cellular or tissue-based product or animal prod-  
6 uct—

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

11 “(2) that is regulated as a device under section  
12 201(h) of the Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 321(h)).”.

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

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

18 (c) IMPLEMENTATION DEADLINES.—

19 (1) STANDARD IDENTIFICATION SYSTEM.—The  
20 Secretary of Veterans Affairs shall adopt or imple-  
21 ment the standard identification system for biologi-  
22 cal implants required by subsection (a) of section  
23 7330C of title 38, United States Code, as added by  
24 subsection (a), with respect to biological implants  
25 described in—

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

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

9 (2) TRACKING SYSTEM.—The Secretary of Vet-  
10 erans Affairs shall implement the biological implant  
11 tracking system required by section 7330C(b) of title  
12 38, United States Code, as added by subsection (a),  
13 by not later than the date that is 180 days after the  
14 date of the enactment of this Act.

15 (d) REPORTING REQUIREMENT.—

16 (1) IN GENERAL.—If the biological implant  
17 tracking system required by section 7330C(b) of title  
18 38, United States Code, as added by subsection (a),  
19 is not operational by the date that is 180 days after  
20 the date of the enactment of this Act, the Secretary  
21 of Veterans Affairs shall submit to the Committee  
22 on Veterans' Affairs of the Senate and the Com-  
23 mittee on Veterans' Affairs of the House of Rep-  
24 resentatives a report explaining why the system is

1 not operational for each month until such time as  
2 the system is operational.

3 (2) ELEMENTS.—Each report submitted under  
4 paragraph (1) shall include a description of the fol-  
5 lowing:

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

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

10 (C) Target dates for a solution to each  
11 such impediment.

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

15 (a) PROCUREMENT.—

16 (1) IN GENERAL.—Subchapter II of chapter 81  
17 of title 38, United States Code, is amended by add-  
18 ing at the end the following new section:

19 **“§ 8129. Procurement of biological implants**

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

23 “(A) The vendor uses the standard identifica-  
24 tion system adopted or implemented by the Sec-  
25 retary under section 7330C(a) of this title and has

1       safeguards to ensure that a distinct identifier has  
2       been in place at each step of distribution of each bio-  
3       logical implant from its donor.

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

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

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

24              “(E) The vendor agrees to notify the Secretary  
25      of any adverse event or reaction report it provides

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

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

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

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

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

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

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

19           “(D) The vendor agrees to notify the Secretary  
20          of any adverse event report it provides to the Food  
21          and Drug Administration as required under part  
22          803 of title 21, Code of Federal Regulations, or any  
23          successor regulation, or any warning letter from the  
24          Food and Drug Administration issued to the vendor  
25          or the original product manufacturer used by the

1 vendor by not later than 60 days after the vendor  
2 receives such report or warning letter.

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

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

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

16 “(C) In the case of biological implants that are un-  
17 available for procurement under the Federal Supply  
18 Schedules, the Secretary shall procure such implants using  
19 competitive procedures in accordance with applicable law  
20 and the Federal Acquisition Regulation, including through  
21 the use of a national contract.

22 “(4) In procuring biological implants under this sec-  
23 tion, the Secretary shall permit a vendor to use any of  
24 the accredited entities identified by the Food and Drug  
25 Administration as an issuing agency pursuant to section

1 830.100 of title 21, Code of Federal Regulations, or any  
2 successor regulation.

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

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

14 “(c) DEFINITIONS.—In this section:

15 “(1) The term ‘biological implant’ has the  
16 meaning given that term in section 7330C(d) of this  
17 title.

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

20 “(A) relates a biological implant to the  
21 human donor of the implant and to all records  
22 pertaining to the implant;

23 “(B) includes information designed to fa-  
24 cilitate effective tracking, using the distinct

1 identification code, from the donor to the recipi-  
2 ent and from the recipient to the donor; and

3 “(C) satisfies the requirements of section  
4 1271.290(c) of title 21, Code of Federal Regu-  
5 lations, or any successor regulation.

6 “(3) The term ‘tissue distribution intermediary’  
7 means an agency that acquires and stores human  
8 tissue for further distribution and performs no other  
9 tissue banking functions.

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

15 (2) CLERICAL AMENDMENT.—The table of sec-  
16 tions at the beginning of chapter 81 is amended by  
17 inserting after the item relating to section 8128 the  
18 following new item:

“8129. Procurement of biological implants.”.

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

24 (c) SPECIAL RULE FOR CRYOPRESERVED PROD-  
25 UCTS.—During the three-year period beginning on the ef-

1 fective date of section 8129 of title 38, United States  
2 Code, as added by subsection (a), biological implants pro-  
3 duced and labeled before that effective date may be pro-  
4 cured by the Department of Veterans Affairs without re-  
5 labeling under the standard identification system adopted  
6 or implemented under section 7330C of such title, as  
7 added by section 2(a).

8 **SEC. 4. FUNDING.**

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

Passed the House of Representatives January 3,  
2017.

Attest:

KAREN L. HAAS,

*Clerk.*