

S 2334

Biological Implant Tracking and Veteran Safety Act of 2015

Congress: 114 (2015–2017, Ended)

Chamber: Senate

Policy Area: Armed Forces and National Security

Introduced: Nov 30, 2015

Current Status: Read twice and referred to the Committee on Veterans' Affairs.

Latest Action: Read twice and referred to the Committee on Veterans' Affairs. (Nov 30, 2015)

Official Text: <https://www.congress.gov/bill/114th-congress/senate-bill/2334>

Sponsor

Name: Sen. Cassidy, Bill [R-LA]

Party: Republican • **State:** LA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Tester, Jon [D-MT]	D · MT		Jan 27, 2016

Committee Activity

Committee	Chamber	Activity	Date
Veterans' Affairs Committee	Senate	Referred To	Nov 30, 2015

Subjects & Policy Tags

Policy Area:

Armed Forces and National Security

Related Bills

Bill	Relationship	Last Action
114 S 2921	Related bill	May 16, 2016: Placed on Senate Legislative Calendar under General Orders. Calendar No. 467.
114 HR 2256	Related bill	Jul 22, 2015: Received in the Senate and Read twice and referred to the Committee on Veterans' Affairs.
114 HR 1016	Related bill	Apr 21, 2015: Forwarded by Subcommittee to Full Committee in the Nature of a Substitute (Amended) by Voice Vote .

Biological Implant Tracking and Veteran Safety Act of 2015

This bill directs the Department of Veterans Affairs (VA) to:

- adopt the unique device identification system developed for medical devices by the Food and Drug Administration (FDA), or implement a comparable standard identification system, for identifying biological implants intended for use in VA medical facilities;
- permit a vendor to use any of the accredited entities identified by the FDA as an issuing agency;
- implement a compatible system for tracking implants from human donor or animal source to implantation; and
- implement inventory controls compatible with such tracking system so that patients who have received a biological implant in a VA medical facility subject to FDA recall can be appropriately notified.

The bill also prescribes requirements for vendors from which the VA may procure biological implants of human origin, and for vendors from which the VA may procure biological implants of non-human origin. Such a vendor must:

- use the standard identification system adopted or implemented by VA under this Act;
- be registered as required by FDA procedures;
- consent to periodic VA inspections and audits regarding records and product handling;
- agree 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, or by FDA request or statutory order;
- agree to notify the VA within 60 days of any adverse event report it provides to the FDA, or of any FDA warning letter issued to the vendor; and
- agree to retain all records associated with the procurement of a biological implant by the VA for at least 10 years.

The VA shall: (1) procure such implants under General Services Administration Federal Supply Schedules if they are available under such Schedules, (2) accommodate reasonable vendor requests to undertake specified outreach efforts to educate VA medical professionals about the use and efficacy of implants, and (3) procure biological implants that are unavailable under such Schedules using competitive procedures in accordance with the Federal Acquisition Regulation.

Any VA procurement employee responsible for a biological implant procurement transaction with intent to avoid, or with reckless disregard of, the requirements of this Act 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.

Certain biological implants may be temporarily procured by the VA without relabeling under the standard identification system.

Actions Timeline

- **Nov 30, 2015:** Introduced in Senate
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