

Calendar No. 75

113TH CONGRESS
1ST SESSION

S. 330

To amend the Public Health Service Act to establish safeguards and standards of quality for research and transplantation of organs infected with human immunodeficiency virus (HIV).

IN THE SENATE OF THE UNITED STATES

FEBRUARY 14, 2013

Mrs. BOXER (for herself, Mr. COBURN, Ms. BALDWIN, Mr. PAUL, Mr. ENZI, Ms. WARREN, Mr. BURR, Mr. KIRK, Mrs. FEINSTEIN, Ms. LANDRIEU, Mr. BLUMENTHAL, and Mr. SCHATZ) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MAY 21, 2013

Reported by Mr. HARKIN, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Public Health Service Act to establish safeguards and standards of quality for research and transplantation of organs infected with human immunodeficiency virus (HIV).

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 “HIV Organ Policy Eq-
3 uity Act”.

4 **SEC. 2. AMENDMENTS TO THE PUBLIC HEALTH SERVICE**
5 **ACT.**

6 (a) **STANDARDS OF QUALITY FOR THE ACQUISITION**
7 **AND TRANSPORTATION OF DONATED ORGANS.—**

8 (1) **ORGAN PROCUREMENT AND TRANSPLAN-**
9 **TATION NETWORK.—**Section 372(b) of the Public
10 Health Service Act (42 U.S.C. 274(b)) is amended—

11 (A) in paragraph (2)(E), by striking “, in-
12 cluding standards for preventing the acquisition
13 of organs that are infected with the etiologic
14 agent for acquired immune deficiency syn-
15 drome”; and

16 (B) by adding at the end the following:

17 “(3) **CLARIFICATION.—**In adopting and using
18 standards of quality under paragraph (2)(E), the
19 Organ Procurement and Transplantation Network
20 may adopt and use such standards with respect to
21 organs infected with human immunodeficiency virus
22 (HIV), provided that any such standards ensure that
23 organs infected with human immunodeficiency virus
24 may be transplanted only into individuals who are
25 infected with such virus before receiving such
26 organ.”.

1 (2) CONFORMING AMENDMENT.—Section
 2 371(b)(3)(C) of the Public Health Service Act (42
 3 U.S.C. 273(b)(3)(C); relating to organ procurement
 4 organizations) is amended by striking “including ar-
 5 ranging for testing with respect to preventing the
 6 acquisition of organs that are infected with the etio-
 7 logic agent for acquired immune deficiency syn-
 8 drome” and inserting “including arranging for test-
 9 ing with respect to identifying organs that are in-
 10 fected with human immunodeficiency virus (HIV)”.

11 (b) PUBLICATION OF RESEARCH GUIDELINES.—Part
 12 H of title III of the Public Health Service Act (42 U.S.C.
 13 273 et seq.) is amended by inserting after section 377D
 14 the following:

15 **“SEC. 377E. GUIDELINES, STANDARDS, AND REGULATIONS**
 16 **WITH RESPECT TO ORGANS INFECTED WITH**
 17 **HIV.**

18 “(a) IN GENERAL.—Not later than 1 year after the
 19 date of the enactment of the HIV Organ Policy Equity
 20 Act, the Secretary shall develop and publish guidelines for
 21 the conduct of research relating to transplantation of or-
 22 gans from donors infected with human immunodeficiency
 23 virus (in this section referred to as ‘HIV’).

24 “(b) CORRESPONDING CHANGES TO STANDARDS AND
 25 REGULATIONS APPLICABLE TO RESEARCH.—Not later

1 than 1 year after the date of the enactment of the HIV
 2 Organ Policy Equity Act, to the extent determined by the
 3 Secretary to be necessary to allow the conduct of research
 4 in accordance with the guidelines developed under sub-
 5 section (a)—

6 “(1) the Organ Procurement and Transplan-
 7 tation Network shall revise the standards of quality
 8 adopted under section 372(b)(2)(E); and

9 “(2) the Secretary shall revise section 121.6 of
 10 title 42, Code of Federal Regulations (or any suc-
 11 cessor regulations).

12 “(c) REVISION OF STANDARDS AND REGULATIONS
 13 GENERALLY.—Not later than 2 years after the date of
 14 the enactment of the HIV Organ Policy Equity Act, and
 15 annually thereafter, the Secretary, shall—

16 “(1) review the results of scientific research in
 17 conjunction with the Organ Procurement and Trans-
 18 plantation Network to determine whether the results
 19 warrant revision of the standards of quality adopted
 20 under section 372(b)(2)(E) with respect to donated
 21 organs infected with HIV and with respect to the
 22 safety of cross-strain transplantation;

23 “(2) if the Secretary determines under para-
 24 graph (1) that such results warrant revision of the
 25 standards of quality adopted under section

1 ~~372(b)(2)(E)~~ with respect to donated organs in-
 2 fected with HIV and with respect to cross-strain
 3 transplantation; direct the Organ Procurement and
 4 Transplantation Network to revise such standards;
 5 consistent with section 372 and in a way that en-
 6 sures the changes will not reduce the safety of organ
 7 transplantation; and

8 “(3) in conjunction with any revision of such
 9 standards under paragraph (2), shall revise section
 10 ~~121.6~~ of title 42, Code of Federal Regulations (or
 11 any successor regulations) for consistency with such
 12 standards.”.

13 **SEC. 3. CONFORMING AMENDMENT TO TITLE 18 OF THE**
 14 **UNITED STATES CODE.**

15 Section ~~1122~~ of title 18, United States Code, is
 16 amended by adding at the end the following:

17 “(d) EXCEPTION.—An organ donation does not vio-
 18 late this section if the donation is in accordance with all
 19 applicable guidelines and regulations of the Secretary
 20 made under section ~~377E~~ of the Public Health Service
 21 Act.”.

22 **SECTION 1. SHORT TITLE.**

23 *This Act may be cited as the “HIV Organ Policy Eq-*
 24 *uity Act”.*

1 **SEC. 2. AMENDMENTS TO THE PUBLIC HEALTH SERVICE**
 2 **ACT.**

3 (a) *STANDARDS OF QUALITY FOR THE ACQUISITION*
 4 *AND TRANSPORTATION OF DONATED ORGANS.—*

5 (1) *ORGAN PROCUREMENT AND TRANSPLAN-*
 6 *TATION NETWORK.—Section 372(b) of the Public*
 7 *Health Service Act (42 U.S.C. 274(b)) is amended—*

8 (A) *in paragraph (2)(E), by striking “, in-*
 9 *cluding standards for preventing the acquisition*
 10 *of organs that are infected with the etiologic*
 11 *agent for acquired immune deficiency syn-*
 12 *drome”; and*

13 (B) *by adding at the end the following:*

14 “(3) *CLARIFICATION.—In adopting and using*
 15 *standards of quality under paragraph (2)(E), the*
 16 *Organ Procurement and Transplantation Network*
 17 *may adopt and use such standards with respect to or-*
 18 *gans infected with human immunodeficiency virus*
 19 *(in this paragraph referred to as ‘HIV’), provided*
 20 *that any such standards ensure that organs infected*
 21 *with HIV may be transplanted only into individuals*
 22 *who—*

23 (A) *are infected with HIV before receiving*
 24 *such organ; and*

25 (B)(i) *are participating in clinical re-*
 26 *search approved by an institutional review board*

under the criteria, standards, and regulations described in subsections (a) and (b) of section 377E; or

“(ii) if the Secretary has determined under section 377E(c) that participation in such clinical research, as a requirement for such transplants, is no longer warranted, are receiving a transplant under the standards and regulations under section 377E(c).”.

(2) *CONFORMING AMENDMENT.*—Section 371(b)(3)(C) of the Public Health Service Act (42 U.S.C. 273(b)(3)(C); relating to organ procurement organizations) is amended by striking “including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome” and inserting “including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV)”.

(3) *TECHNICAL AMENDMENTS.*—Section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) is amended by—

(A) striking subparagraph (E);

(B) redesignating subparagraphs (F) and

(G) as subparagraphs (E) and (F), respectively;

1 (C) striking “(H) has a director” and in-
 2 serting “(G) has a director”; and

3 (D) in subparagraph (H)—

4 (i) in clause (i) (V), by striking “para-
 5 graph (2)(G)” and inserting “paragraph
 6 (3)(G)”; and

7 (ii) in clause (ii), by striking “para-
 8 graph (2)” and inserting “paragraph (3)”.

9 (b) *PUBLICATION OF RESEARCH GUIDELINES.*—Part
 10 *H of title III of the Public Health Service Act (42 U.S.C.*
 11 *273 et seq.) is amended by inserting after section 377D the*
 12 *following:*

13 **“SEC. 377E. CRITERIA, STANDARDS, AND REGULATIONS**
 14 **WITH RESPECT TO ORGANS INFECTED WITH**
 15 **HIV.**

16 “(a) *IN GENERAL.*—Not later than 2 years after the
 17 *date of the enactment of the HIV Organ Policy Equity Act,*
 18 *the Secretary shall develop and publish criteria for the con-*
 19 *duct of research relating to transplantation of organs from*
 20 *donors infected with human immunodeficiency virus (in*
 21 *this section referred to as ‘HIV’) into individuals who are*
 22 *infected with HIV before receiving such organ.*

23 “(b) *CORRESPONDING CHANGES TO STANDARDS AND*
 24 *REGULATIONS APPLICABLE TO RESEARCH.*—Not later than
 25 *2 years after the date of the enactment of the HIV Organ*

1 *Policy Equity Act, to the extent determined by the Secretary*
 2 *to be necessary to allow the conduct of research in accord-*
 3 *ance with the criteria developed under subsection (a)—*

4 “(1) *the Organ Procurement and Transplan-*
 5 *tation Network shall revise the standards of quality*
 6 *adopted under section 372(b)(2)(E); and*

7 “(2) *the Secretary shall revise section 121.6 of*
 8 *title 42, Code of Federal Regulations (or any suc-*
 9 *cessor regulations).*

10 “(c) *REVISION OF STANDARDS AND REGULATIONS*
 11 *GENERALLY.—Not later than 4 years after the date of the*
 12 *enactment of the HIV Organ Policy Equity Act, and annu-*
 13 *ally thereafter, the Secretary, shall—*

14 “(1) *review the results of scientific research in*
 15 *conjunction with the Organ Procurement and Trans-*
 16 *plantation Network to determine whether the results*
 17 *warrant revision of the standards of quality adopted*
 18 *under section 372(b)(2)(E) with respect to donated or-*
 19 *gans infected with HIV and with respect to the safety*
 20 *of transplanting an organ with a particular strain of*
 21 *HIV into a recipient with a different strain of HIV;*

22 “(2) *if the Secretary determines under para-*
 23 *graph (1) that such results warrant revision of the*
 24 *standards of quality adopted under section*
 25 *372(b)(2)(E) with respect to donated organs infected*

1 *with HIV and with respect to transplanting an organ*
 2 *with a particular strain of HIV into a recipient with*
 3 *a different strain of HIV, direct the Organ Procure-*
 4 *ment and Transplantation Network to revise such*
 5 *standards, consistent with section 372 and in a way*
 6 *that ensures the changes will not reduce the safety of*
 7 *organ transplantation; and*

8 *“(3) in conjunction with any revision of such*
 9 *standards under paragraph (2), revise section 121.6*
 10 *of title 42, Code of Federal Regulations (or any suc-*
 11 *cessor regulations).”.*

12 **SEC. 3. CONFORMING AMENDMENT TO TITLE 18 OF THE**
 13 **UNITED STATES CODE.**

14 *Section 1122 of title 18, United States Code, is amend-*
 15 *ed by adding at the end the following:*

16 *“(d) EXCEPTION.—An organ donation does not violate*
 17 *this section if the donation is in accordance with all appli-*
 18 *cable criteria and regulations of the Secretary made under*
 19 *section 377E of the Public Health Service Act.”.*

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