

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, and Mr. PAUL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “HIV Organ Policy Eq-
5 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
 18 organs infected with human immunodeficiency virus
 19 (HIV), provided that any such standards ensure that
 20 organs infected with human immunodeficiency virus
 21 may be transplanted only into individuals who are
 22 infected with such virus before receiving such
 23 organ.”.

24 (2) CONFORMING AMENDMENT.—Section
 25 371(b)(3)(C) of the Public Health Service Act (42
 26 U.S.C. 273(b)(3)(C); relating to organ procurement

1 organizations) is amended by striking “including ar-
 2 ranging for testing with respect to preventing the
 3 acquisition of organs that are infected with the etio-
 4 logic agent for acquired immune deficiency syn-
 5 drome” and inserting “including arranging for test-
 6 ing with respect to identifying organs that are in-
 7 fected with human immunodeficiency virus (HIV)”.

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

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

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

21 “(b) CORRESPONDING CHANGES TO STANDARDS AND
 22 REGULATIONS APPLICABLE TO RESEARCH.—Not later
 23 than 1 year after the date of the enactment of the HIV
 24 Organ Policy Equity Act, to the extent determined by the
 25 Secretary to be necessary to allow the conduct of research

1 in accordance with the guidelines developed under sub-
 2 section (a)—

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

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

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

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

20 “(2) if the Secretary determines under para-
 21 graph (1) that such results warrant revision of the
 22 standards of quality adopted under section
 23 372(b)(2)(E) with respect to donated organs in-
 24 fected with HIV and with respect to cross-strain
 25 transplantation, direct the Organ Procurement and

1 Transplantation Network to revise such standards,
 2 consistent with section 372 and in a way that en-
 3 sures the changes will not reduce the safety of organ
 4 transplantation; and

5 “(3) in conjunction with any revision of such
 6 standards under paragraph (2), shall revise section
 7 121.6 of title 42, Code of Federal Regulations (or
 8 any successor regulations) for consistency with such
 9 standards.”.

10 **SEC. 3. CONFORMING AMENDMENT TO TITLE 18 OF THE**
 11 **UNITED STATES CODE.**

12 Section 1122 of title 18, United States Code, is
 13 amended by adding at the end the following:

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

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