

113TH CONGRESS  
1ST SESSION

# S. 330

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## AN ACT

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 (in this paragraph referred to as ‘HIV’), provided  
23 that any such standards ensure that organs infected  
24 with HIV may be transplanted only into individuals  
25 who—

1           “(A) are infected with HIV before receiv-  
2           ing such organ; and

3           “(B)(i) are participating in clinical re-  
4           search approved by an institutional review  
5           board under the criteria, standards, and regula-  
6           tions described in subsections (a) and (b) of  
7           section 377E; or

8           “(ii) if the Secretary has determined under  
9           section 377E(c) that participation in such clin-  
10          ical research, as a requirement for such trans-  
11          plants, is no longer warranted, are receiving a  
12          transplant under the standards and regulations  
13          under section 377E(c).”.

14          (2)     CONFORMING     AMENDMENT.—Section  
15          371(b)(3)(C) of the Public Health Service Act (42  
16          U.S.C. 273(b)(3)(C); relating to organ procurement  
17          organizations) is amended by striking “including ar-  
18          ranging for testing with respect to preventing the  
19          acquisition of organs that are infected with the etio-  
20          logic agent for acquired immune deficiency syn-  
21          drome” and inserting “including arranging for test-  
22          ing with respect to identifying organs that are in-  
23          fected with human immunodeficiency virus (HIV)”.

1           (3)     TECHNICAL     AMENDMENTS.—Section  
2     371(b)(1) of the Public Health Service Act (42  
3     U.S.C. 273(b)(1)) is amended by—

4           (A) striking subparagraph (E);

5           (B) redesignating subparagraphs (F) and  
6     (G) as subparagraphs (E) and (F), respectively;

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

9           (D) in subparagraph (H)—

10           (i) in clause (i) (V), by striking “para-  
11     graph (2)(G)” and inserting “paragraph  
12     (3)(G)”; and

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

15     (b) PUBLICATION OF RESEARCH GUIDELINES.—Part  
16     H of title III of the Public Health Service Act (42 U.S.C.  
17     273 et seq.) is amended by inserting after section 377D  
18     the following:

19     “**SEC. 377E. CRITERIA, STANDARDS, AND REGULATIONS**  
20           **WITH RESPECT TO ORGANS INFECTED WITH**  
21           **HIV.**”

22     “(a) IN GENERAL.—Not later than 2 years after the  
23     date of the enactment of the HIV Organ Policy Equity  
24     Act, the Secretary shall develop and publish criteria for  
25     the conduct of research relating to transplantation of or-

1 gans from donors infected with human immunodeficiency  
2 virus (in this section referred to as ‘HIV’) into individuals  
3 who are infected with HIV before receiving such organ.

4 “(b) CORRESPONDING CHANGES TO STANDARDS AND  
5 REGULATIONS APPLICABLE TO RESEARCH.—Not later  
6 than 2 years after the date of the enactment of the HIV  
7 Organ Policy Equity Act, to the extent determined by the  
8 Secretary to be necessary to allow the conduct of research  
9 in accordance with the criteria developed under subsection  
10 (a)—

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

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

17 “(c) REVISION OF STANDARDS AND REGULATIONS  
18 GENERALLY.—Not later than 4 years after the date of  
19 the enactment of the HIV Organ Policy Equity Act, and  
20 annually thereafter, the Secretary, shall—

21 “(1) review the results of scientific research in  
22 conjunction with the Organ Procurement and Trans-  
23 plantation Network to determine whether the results  
24 warrant revision of the standards of quality adopted  
25 under section 372(b)(2)(E) with respect to donated

1 organs infected with HIV and with respect to the  
 2 safety of transplanting an organ with a particular  
 3 strain of HIV into a recipient with a different strain  
 4 of HIV;

5 “(2) if the Secretary determines under para-  
 6 graph (1) that such results warrant revision of the  
 7 standards of quality adopted under section  
 8 372(b)(2)(E) with respect to donated organs in-  
 9 fected with HIV and with respect to transplanting  
 10 an organ with a particular strain of HIV into a re-  
 11 cipient with a different strain of HIV, direct the  
 12 Organ Procurement and Transplantation Network to  
 13 revise such standards, consistent with section 372  
 14 and in a way that ensures the changes will not re-  
 15 duce the safety of organ transplantation; and

16 “(3) in conjunction with any revision of such  
 17 standards under paragraph (2), revise section 121.6  
 18 of title 42, Code of Federal Regulations (or any suc-  
 19 cessor regulations).”.

20 **SEC. 3. CONFORMING AMENDMENT TO TITLE 18 OF THE**  
 21 **UNITED STATES CODE.**

22 Section 1122(a) of title 18, United States Code, is  
 23 amended by inserting “or in accordance with all applicable  
 24 guidelines and regulations made by the Secretary of

- 1 Health and Human Services under section 377E of the
- 2 Public Health Service Act” after “research or testing”.

Passed the Senate June 17, 2013.

Attest:

*Secretary.*

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