

113TH CONGRESS  
1ST SESSION

# H. R. 698

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).

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2013

Mrs. CAPPS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## 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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