

One Hundred Thirteenth Congress
of the
United States of America

AT THE FIRST SESSION

*Begun and held at the City of Washington on Thursday,
the third day of January, two thousand and thirteen*

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).

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “HIV Organ Policy Equity Act”.

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

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

(1) ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.—Section 372(b) of the Public Health Service Act (42 U.S.C. 274(b)) is amended—

(A) in paragraph (2)(E), by striking “, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome”; and

(B) by adding at the end the following:

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

“(A) are infected with HIV before receiving such organ;
and

“(B)(i) are participating in clinical research 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;
- (C) striking “(H) has a director” and inserting “(G) has a director”; and
- (D) in subparagraph (H)—
 - (i) in clause (i) (V), by striking “paragraph (2)(G)” and inserting “paragraph (3)(G)”; and
 - (ii) in clause (ii), by striking “paragraph (2)” and inserting “paragraph (3)”.

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

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

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

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

“(1) the Organ Procurement and Transplantation Network shall revise the standards of quality adopted under section 372(b)(2)(E); and

“(2) the Secretary shall revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

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

“(1) review the results of scientific research in conjunction with the Organ Procurement and Transplantation Network to determine whether the results warrant revision of the standards of quality adopted under section 372(b)(2)(E) with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV;

“(2) if the Secretary determines under paragraph (1) that such results warrant revision of the standards of quality adopted under section 372(b)(2)(E) with respect to donated organs infected with HIV and with respect to transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV, direct the Organ Procurement and

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Transplantation Network to revise such standards, consistent with section 372 and in a way that ensures the changes will not reduce the safety of organ transplantation; and

“(3) in conjunction with any revision of such standards under paragraph (2), revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).”.

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

Section 1122(a) of title 18, United States Code, is amended by inserting “or in accordance with all applicable guidelines and regulations made by the Secretary of Health and Human Services under section 377E of the Public Health Service Act” after “research or testing”.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*