

for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

(July 1, 1944, ch. 373, title III, §377C, as added Pub. L. 108-216, §5, Apr. 5, 2004, 118 Stat. 587.)

§ 274f-4. Report relating to organ donation and the recovery, preservation, and transportation of organs

(a) In general

Not later than December 31, 2005, and every 2 years thereafter, the Secretary shall report to the appropriate committees of Congress on the activities of the Department carried out pursuant to this part, including an evaluation describing the extent to which the activities have affected the rate of organ donation and recovery.

(b) Requirements

To the extent practicable, each report submitted under subsection (a) shall—

- (1) evaluate the effectiveness of activities, identify effective activities, and disseminate such findings with respect to organ donation and recovery;
- (2) assess organ donation and recovery activities that are recently completed, ongoing, or planned; and
- (3) evaluate progress on the implementation of the plan required under subsection (c)(5).

(c) Initial report requirements

The initial report under subsection (a) shall include the following:

- (1) An evaluation of the organ donation practices of organ procurement organizations, States, other countries, and other appropriate organizations including an examination across all populations, including those with low organ donation rates, of—

- (A) existing barriers to organ donation; and
- (B) the most effective donation and recovery practices.

- (2) An evaluation of living donation practices and procedures. Such evaluation shall include an assessment of issues relating to informed consent and the health risks associated with living donation (including possible reduction of long-term effects).

- (3) An evaluation of—

- (A) federally supported or conducted organ donation efforts and policies, as well as federally supported or conducted basic, clinical, and health services research (including research on preservation techniques and organ rejection and compatibility); and

- (B) the coordination of such efforts across relevant agencies within the Department and throughout the Federal Government.

- (4) An evaluation of the costs and benefits of State donor registries, including the status of existing State donor registries, the effect of State donor registries on organ donation rates, issues relating to consent, and recommendations regarding improving the effectiveness of State donor registries in increasing overall organ donation rates.

- (5) A plan to improve federally supported or conducted organ donation and recovery activi-

ties, including, when appropriate, the establishment of baselines and benchmarks to measure overall outcomes of these programs. Such plan shall provide for the ongoing coordination of federally supported or conducted organ donation and research activities.

(July 1, 1944, ch. 373, title III, §377D, as added Pub. L. 108-216, §6, Apr. 5, 2004, 118 Stat. 588.)

§ 274f-5. Criteria, standards, and regulations with respect to organs infected with HIV

(a) In general

Not later than 2 years after November 21, 2013, 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 November 21, 2013, 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 274(b)(2)(E) of this title; 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 November 21, 2013, and annually thereafter, the Secretary,¹ 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 274(b)(2)(E) of this title 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 274(b)(2)(E) of this title 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 Transplantation Network to revise such standards, consistent with section 274 of this title 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).

(July 1, 1944, ch. 373, title III, §377E, as added Pub. L. 113-51, §2(b), Nov. 21, 2013, 127 Stat. 580.)

¹ So in original. The comma probably should not appear.