

PUBLIC LAW 108-216—APR. 5, 2004

ORGAN DONATION AND RECOVERY  
IMPROVEMENT ACT

Public Law 108–216  
108th Congress

An Act

Apr. 5, 2004  
[H.R. 3926]

To amend the Public Health Service Act to promote organ donation, and for other purposes.

Organ Donation  
and Recovery  
Improvement  
Act.  
42 USC 201 note.

*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 “Organ Donation and Recovery Improvement Act”.

**SEC. 2. SENSE OF CONGRESS.**

(a) **PUBLIC AWARENESS OF NEED FOR ORGAN DONATION.**—It is the sense of Congress that the Federal Government should carry out programs to educate the public with respect to organ donation, including the need to provide for an adequate rate of such donations.

(b) **FAMILY DISCUSSIONS OF ORGAN DONATIONS.**—Congress recognizes the importance of families pledging to each other to share their lives as organ and tissue donors and acknowledges the importance of discussing organ and tissue donation as a family.

(c) **LIVING DONATIONS OF ORGANS.**—Congress—

(1) recognizes the generous contribution made by each living individual who has donated an organ to save a life; and

(2) acknowledges the advances in medical technology that have enabled organ transplantation with organs donated by living individuals to become a viable treatment option for an increasing number of patients.

**SEC. 3. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION.**

Section 377 of the Public Health Service Act (42 U.S.C. 274f) is amended to read as follows:

**“SEC. 377. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION.**

“(a) **IN GENERAL.**—The Secretary may award grants to States, transplant centers, qualified organ procurement organizations under section 371, or other public or private entities for the purpose of—

“(1) providing for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred to as ‘donating individuals’); and

“(2) providing for the reimbursement of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

“(b) PREFERENCE.—The Secretary shall, in carrying out subsection (a), give preference to those individuals that the Secretary determines are more likely to be otherwise unable to meet such expenses.

“(c) CERTAIN CIRCUMSTANCES.—The Secretary may, in carrying out subsection (a), consider—

“(1) the term ‘donating individuals’ as including individuals who in good faith incur qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs; and

“(2) the term ‘qualifying expenses’ as including the expenses of having relatives or other individuals, not to exceed 2, accompany or assist the donating individual for purposes of subsection (a) (subject to making payment for only those types of expenses that are paid for a donating individual).

“(d) RELATIONSHIP TO PAYMENTS UNDER OTHER PROGRAMS.—An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

“(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program;

“(2) by an entity that provides health services on a prepaid basis; or

“(3) by the recipient of the organ.

“(e) DEFINITIONS.—For purposes of this section:

“(1) The term ‘donating individuals’ has the meaning indicated for such term in subsection (a)(1), subject to subsection (c)(1).

“(2) The term ‘qualifying expenses’ means the expenses authorized for purposes of subsection (a), subject to subsection (c)(2).

“(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$5,000,000 for each of the fiscal years 2005 through 2009.”

#### SEC. 4. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.

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

##### “SEC. 377A. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.

“(a) ORGAN DONATION PUBLIC AWARENESS PROGRAM.—The Secretary shall, directly or through grants or contracts, establish a public education program in cooperation with existing national public awareness campaigns to increase awareness about organ donation and the need to provide for an adequate rate of such donations.

“(b) STUDIES AND DEMONSTRATIONS.—The Secretary may make peer-reviewed grants to, or enter into peer-reviewed contracts with, public and nonprofit private entities for the purpose of carrying out studies and demonstration projects to increase organ donation and recovery rates, including living donation.

“(c) GRANTS TO STATES.—

“(1) IN GENERAL.—The Secretary may make grants to States for the purpose of assisting States in carrying out organ

Grants.  
Contracts.  
42 USC 274f-1.

donor awareness, public education, and outreach activities and programs designed to increase the number of organ donors within the State, including living donors.

“(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, a State shall—

“(A) submit an application to the Department in the form prescribed;

“(B) establish yearly benchmarks for improvement in organ donation rates in the State; and

Reports.

“(C) report to the Secretary on an annual basis a description and assessment of the State’s use of funds received under this subsection, accompanied by an assessment of initiatives for potential replication in other States.

“(3) USE OF FUNDS.—Funds received under this subsection may be used by the State, or in partnership with other public agencies or private sector institutions, for education and awareness efforts, information dissemination, activities pertaining to the State donor registry, and other innovative donation specific initiatives, including living donation.

“(d) EDUCATIONAL ACTIVITIES.—The Secretary, in coordination with the Organ Procurement and Transplantation Network and other appropriate organizations, shall support the development and dissemination of educational materials to inform health care professionals and other appropriate professionals in issues surrounding organ, tissue, and eye donation including evidence-based proven methods to approach patients and their families, cultural sensitivities, and other relevant issues.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$15,000,000 for fiscal year 2005, and such sums as may be necessary for each of the fiscal years 2006 through 2009. Such authorization of appropriations is in addition to any other authorizations of appropriations that are available for such purpose.

42 USC 274f-2.

**“SEC. 377B. GRANTS REGARDING HOSPITAL ORGAN DONATION COORDINATORS.**

“(a) AUTHORITY.—

“(1) IN GENERAL.—The Secretary may award grants to qualified organ procurement organizations and hospitals under section 371 to establish programs coordinating organ donation activities of eligible hospitals and qualified organ procurement organizations under section 371. Such activities shall be coordinated to increase the rate of organ donations for such hospitals.

“(2) ELIGIBLE HOSPITAL.—For purposes of this section, the term ‘eligible hospital’ means a hospital that performs significant trauma care, or a hospital or consortium of hospitals that serves a population base of not fewer than 200,000 individuals.

“(b) ADMINISTRATION OF COORDINATION PROGRAM.—A condition for the receipt of a grant under subsection (a) is that the applicant involved agree that the program under such subsection will be carried out jointly—

“(1) by representatives from the eligible hospital and the qualified organ procurement organization with respect to which the grant is made; and

“(2) by such other entities as the representatives referred to in paragraph (1) may designate.

“(c) REQUIREMENTS.—Each entity receiving a grant under subsection (a) shall—

“(1) establish joint organ procurement organization and hospital designated leadership responsibility and accountability for the project;

“(2) develop mutually agreed upon overall project performance goals and outcome measures, including interim outcome targets; and

“(3) collaboratively design and implement an appropriate data collection process to provide ongoing feedback to hospital and organ procurement organization leadership on project progress and results.

“(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to interfere with regulations in force on the date of enactment of the Organ Donation and Recovery Improvement Act.

“(e) EVALUATIONS.—Within 3 years after the award of grants under this section, the Secretary shall ensure an evaluation of programs carried out pursuant to subsection (a) in order to determine the extent to which the programs have increased the rate of organ donation for the eligible hospitals involved.

Deadline.

“(f) MATCHING REQUIREMENT.—The Secretary may not award a grant to a qualifying organ donation entity under this section unless such entity agrees that, with respect to costs to be incurred by the entity in carrying out activities for which the grant was awarded, the entity shall contribute (directly or through donations from public or private entities) non-Federal contributions in cash or in kind, in an amount equal to not less than 30 percent of the amount of the grant awarded to such entity.

“(g) FUNDING.—For the purpose of carrying out this section, there are authorized to be appropriated \$3,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.”

**SEC. 5. STUDIES RELATING TO ORGAN DONATION AND THE RECOVERY, PRESERVATION, AND TRANSPORTATION OF ORGANS.**

Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by inserting after section 377B, as added by section 4, the following:

**“SEC. 377C. STUDIES RELATING TO ORGAN DONATION AND THE RECOVERY, PRESERVATION, AND TRANSPORTATION OF ORGANS.**

42 USC 274f-3.

“(a) DEVELOPMENT OF SUPPORTIVE INFORMATION.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall develop scientific evidence in support of efforts to increase organ donation and improve the recovery, preservation, and transportation of organs.

“(b) ACTIVITIES.—In carrying out subsection (a), the Secretary shall—

“(1) conduct or support evaluation research to determine whether interventions, technologies, or other activities improve the effectiveness, efficiency, or quality of existing organ donation practice;

“(2) undertake or support periodic reviews of the scientific literature to assist efforts of professional societies to ensure that the clinical practice guidelines that they develop reflect the latest scientific findings;

“(3) ensure that scientific evidence of the research and other activities undertaken under this section is readily accessible by the organ procurement workforce; and

“(4) work in coordination with the appropriate professional societies as well as the Organ Procurement and Transplantation Network and other organ procurement and transplantation organizations to develop evidence and promote the adoption of such proven practices.

“(c) RESEARCH AND DISSEMINATION.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, as appropriate, shall provide support for research and dissemination of findings, to—

“(1) develop a uniform clinical vocabulary for organ recovery;

“(2) apply information technology and telecommunications to support the clinical operations of organ procurement organizations;

“(3) enhance the skill levels of the organ procurement workforce in undertaking quality improvement activities; and

“(4) assess specific organ recovery, preservation, and transportation technologies.

“(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated \$2,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.”

**SEC. 6. REPORT RELATING TO ORGAN DONATION AND THE RECOVERY, PRESERVATION, AND TRANSPORTATION OF ORGANS.**

Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by inserting after section 377C, as added by section 5, the following:

42 USC 274f-4.

**“SEC. 377D. REPORT RELATING TO ORGAN DONATION AND THE RECOVERY, PRESERVATION, AND TRANSPORTATION OF ORGANS.**

Deadline.

“(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 activities, 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.”.

**SEC. 7. NATIONAL LIVING DONOR MECHANISMS.**

Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by inserting after section 371 the following:

**“SEC. 371A. NATIONAL LIVING DONOR MECHANISMS.**

42 USC 273a.

“The Secretary may establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations by individuals who have served as living donors.”.

**SEC. 8. STUDY.**

Deadline.  
Reports.

Not later than December 31, 2004, the Secretary of Health and Human Services, in consultation with appropriate entities, including advocacy groups representing those populations that are likely to be disproportionately affected by proposals to increase cadaveric donation, shall submit to the appropriate committees of Congress a report that evaluates the ethical implications of such proposals.

**SEC. 9. QUALIFIED ORGAN PROCUREMENT ORGANIZATIONS.**

Section 371(a) of the Public Health Service Act (42 U.S.C. 273(a)) is amended by striking paragraph (3).

Approved April 5, 2004.

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**LEGISLATIVE HISTORY—H.R. 3926:**

CONGRESSIONAL RECORD, Vol. 150 (2004):

Mar. 23, 24, considered and passed House.

Mar. 25, considered and passed Senate.

