

108TH CONGRESS
2^D SESSION

H. R. 3926

IN THE SENATE OF THE UNITED STATES

MARCH 25, 2004

Received

AN ACT

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

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 “Organ Donation and
3 Recovery Improvement Act”.

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

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

10 (b) FAMILY DISCUSSIONS OF ORGAN DONATIONS.—
11 Congress recognizes the importance of families pledging
12 to each other to share their lives as organ and tissue do-
13 nors and acknowledges the importance of discussing organ
14 and tissue donation as a family.

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

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

19 (2) acknowledges the advances in medical tech-
20 nology that have enabled organ transplantation with
21 organs donated by living individuals to become a via-
22 ble treatment option for an increasing number of pa-
23 tients.

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

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

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

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

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

17 “(2) providing for the reimbursement of such
18 incidental nonmedical expenses that are so incurred
19 as the Secretary determines by regulation to be ap-
20 propriate.

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

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

1 “(1) the term ‘donating individuals’ as includ-
2 ing individuals who in good faith incur qualifying ex-
3 penses toward the intended donation of an organ but
4 with respect to whom, for such reasons as the Sec-
5 retary determines to be appropriate, no donation of
6 the organ occurs; and

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

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

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

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

25 “(3) by the recipient of the organ.

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

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

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

8 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
9 purpose of carrying out this section, there is authorized
10 to be appropriated \$5,000,000 for each of the fiscal years
11 2005 through 2009.”.

12 **SEC. 4. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.**
13 **TIONS.**

14 Part H of title III of the Public Health Service Act
15 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
16 tion 377 the following:

17 **“SEC. 377A. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.**
18 **ONSTRATIONS.**

19 “(a) ORGAN DONATION PUBLIC AWARENESS PRO-
20 GRAM.—The Secretary shall, directly or through grants or
21 contracts, establish a public education program in co-
22 operation with existing national public awareness cam-
23 paigns to increase awareness about organ donation and
24 the need to provide for an adequate rate of such donations.

1 “(b) STUDIES AND DEMONSTRATIONS.—The Sec-
2 retary may make peer-reviewed grants to, or enter into
3 peer-reviewed contracts with, public and nonprofit private
4 entities for the purpose of carrying out studies and dem-
5 onstration projects to increase organ donation and recov-
6 ery rates, including living donation.

7 “(c) GRANTS TO STATES.—

8 “(1) IN GENERAL.—The Secretary may make
9 grants to States for the purpose of assisting States
10 in carrying out organ donor awareness, public edu-
11 cation, and outreach activities and programs de-
12 signed to increase the number of organ donors with-
13 in the State, including living donors.

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

16 “(A) submit an application to the Depart-
17 ment in the form prescribed;

18 “(B) establish yearly benchmarks for im-
19 provement in organ donation rates in the State;
20 and

21 “(C) report to the Secretary on an annual
22 basis a description and assessment of the
23 State’s use of funds received under this sub-
24 section, accompanied by an assessment of ini-
25 tiatives for potential replication in other States.

1 “(3) USE OF FUNDS.—Funds received under
2 this subsection may be used by the State, or in part-
3 nership with other public agencies or private sector
4 institutions, for education and awareness efforts, in-
5 formation dissemination, activities pertaining to the
6 State donor registry, and other innovative donation
7 specific initiatives, including living donation.

8 “(d) EDUCATIONAL ACTIVITIES.—The Secretary, in
9 coordination with the Organ Procurement and Transplan-
10 tation Network and other appropriate organizations, shall
11 support the development and dissemination of educational
12 materials to inform health care professionals and other ap-
13 propriate professionals in issues surrounding organ, tis-
14 sue, and eye donation including evidence-based proven
15 methods to approach patients and their families, cultural
16 sensitivities, and other relevant issues.

17 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
18 purpose of carrying out this section, there are authorized
19 to be appropriated \$15,000,000 for fiscal year 2005, and
20 such sums as may be necessary for each of the fiscal years
21 2006 through 2009. Such authorization of appropriations
22 is in addition to any other authorizations of appropriations
23 that are available for such purpose.

1 **“SEC. 377B. GRANTS REGARDING HOSPITAL ORGAN DONA-**
2 **TION COORDINATORS.**

3 “(a) AUTHORITY.—

4 “(1) IN GENERAL.—The Secretary may award
5 grants to qualified organ procurement organizations
6 and hospitals under section 371 to establish pro-
7 grams coordinating organ donation activities of eligi-
8 ble hospitals and qualified organ procurement orga-
9 nizations under section 371. Such activities shall be
10 coordinated to increase the rate of organ donations
11 for such hospitals.

12 “(2) ELIGIBLE HOSPITAL.—For purposes of
13 this section, the term ‘eligible hospital’ means a hos-
14 pital that performs significant trauma care, or a
15 hospital or consortium of hospitals that serves a
16 population base of not fewer than 200,000 individ-
17 uals.

18 “(b) ADMINISTRATION OF COORDINATION PRO-
19 GRAM.—A condition for the receipt of a grant under sub-
20 section (a) is that the applicant involved agree that the
21 program under such subsection will be carried out joint-
22 ly—

23 “(1) by representatives from the eligible hos-
24 pital and the qualified organ procurement organiza-
25 tion with respect to which the grant is made; and

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

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

5 “(1) establish joint organ procurement organi-
6 zation and hospital designated leadership responsi-
7 bility and accountability for the project;

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

11 “(3) collaboratively design and implement an
12 appropriate data collection process to provide ongo-
13 ing feedback to hospital and organ procurement or-
14 ganization leadership on project progress and re-
15 sults.

16 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
17 tion shall be construed to interfere with regulations in
18 force on the date of enactment of the Organ Donation and
19 Recovery Improvement Act.

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

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

10 “(g) FUNDING.—For the purpose of carrying out this
11 section, there are authorized to be appropriated
12 \$3,000,000 for fiscal year 2005, and such sums as may
13 be necessary for each of fiscal years 2006 through 2009.”.

14 **SEC. 5. STUDIES RELATING TO ORGAN DONATION AND THE**
15 **RECOVERY, PRESERVATION, AND TRANSPOR-**
16 **TATION OF ORGANS.**

17 Part H of title III of the Public Health Service Act
18 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
19 tion 377B, as added by section 4, the following:

20 **“SEC. 377C. STUDIES RELATING TO ORGAN DONATION AND**
21 **THE RECOVERY, PRESERVATION, AND TRANS-**
22 **PORTATION OF ORGANS.**

23 “(a) DEVELOPMENT OF SUPPORTIVE INFORMA-
24 TION.—The Secretary, acting through the Director of the
25 Agency for Healthcare Research and Quality, shall develop

1 scientific evidence in support of efforts to increase organ
2 donation and improve the recovery, preservation, and
3 transportation of organs.

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

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

10 “(2) undertake or support periodic reviews of
11 the scientific literature to assist efforts of profes-
12 sional societies to ensure that the clinical practice
13 guidelines that they develop reflect the latest sci-
14 entific findings;

15 “(3) ensure that scientific evidence of the re-
16 search and other activities undertaken under this
17 section is readily accessible by the organ procure-
18 ment workforce; and

19 “(4) work in coordination with the appropriate
20 professional societies as well as the Organ Procure-
21 ment and Transplantation Network and other organ
22 procurement and transplantation organizations to
23 develop evidence and promote the adoption of such
24 proven practices.

1 “(c) RESEARCH AND DISSEMINATION.—The Sec-
2 retary, acting through the Director of the Agency for
3 Healthcare Research and Quality, as appropriate, shall
4 provide support for research and dissemination of find-
5 ings, to—

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

8 “(2) apply information technology and tele-
9 communications to support the clinical operations of
10 organ procurement organizations;

11 “(3) enhance the skill levels of the organ pro-
12 curement workforce in undertaking quality improve-
13 ment activities; and

14 “(4) assess specific organ recovery, preserva-
15 tion, and transportation technologies.

16 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
17 purpose of carrying out this section, there are authorized
18 to be appropriated \$2,000,000 for fiscal year 2005, and
19 such sums as may be necessary for each of fiscal years
20 2006 through 2009.”.

1 **SEC. 6. REPORT RELATING TO ORGAN DONATION AND THE**
2 **RECOVERY, PRESERVATION, AND TRANSPOR-**
3 **TATION OF ORGANS.**

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

7 **“SEC. 377D. REPORT RELATING TO ORGAN DONATION AND**
8 **THE RECOVERY, PRESERVATION, AND TRANS-**
9 **PORTATION OF ORGANS.**

10 “(a) IN GENERAL.—Not later than December 31,
11 2005, and every 2 years thereafter, the Secretary shall re-
12 port to the appropriate committees of Congress on the ac-
13 tivities of the Department carried out pursuant to this
14 part, including an evaluation describing the extent to
15 which the activities have affected the rate of organ dona-
16 tion and recovery.

17 “(b) REQUIREMENTS.—To the extent practicable,
18 each report submitted under subsection (a) shall—

19 “(1) evaluate the effectiveness of activities,
20 identify effective activities, and disseminate such
21 findings with respect to organ donation and recov-
22 ery;

23 “(2) assess organ donation and recovery activi-
24 ties that are recently completed, ongoing, or
25 planned; and

1 “(3) evaluate progress on the implementation of
2 the plan required under subsection (c)(5).

3 “(c) INITIAL REPORT REQUIREMENTS.—The initial
4 report under subsection (a) shall include the following:

5 “(1) An evaluation of the organ donation prac-
6 tices of organ procurement organizations, States,
7 other countries, and other appropriate organizations
8 including an examination across all populations, in-
9 cluding those with low organ donation rates, of—

10 “(A) existing barriers to organ donation;

11 and

12 “(B) the most effective donation and re-
13 covery practices.

14 “(2) An evaluation of living donation practices
15 and procedures. Such evaluation shall include an as-
16 sessment of issues relating to informed consent and
17 the health risks associated with living donation (in-
18 cluding possible reduction of long-term effects).

19 “(3) An evaluation of—

20 “(A) federally supported or conducted
21 organ donation efforts and policies, as well as
22 federally supported or conducted basic, clinical,
23 and health services research (including research
24 on preservation techniques and organ rejection
25 and compatibility); and

1 “(B) the coordination of such efforts
2 across relevant agencies within the Department
3 and throughout the Federal Government.

4 “(4) An evaluation of the costs and benefits of
5 State donor registries, including the status of exist-
6 ing State donor registries, the effect of State donor
7 registries on organ donation rates, issues relating to
8 consent, and recommendations regarding improving
9 the effectiveness of State donor registries in increas-
10 ing overall organ donation rates.

11 “(5) A plan to improve federally supported or
12 conducted organ donation and recovery activities, in-
13 cluding, when appropriate, the establishment of
14 baselines and benchmarks to measure overall out-
15 comes of these programs. Such plan shall provide for
16 the ongoing coordination of federally supported or
17 conducted organ donation and research activities.”.

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

19 Part H of title III of the Public Health Service Act
20 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
21 tion 371 the following:

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

23 “The Secretary may establish and maintain mecha-
24 nisms to evaluate the long-term effects associated with liv-

1 ing organ donations by individuals who have served as liv-
2 ing donors.”.

3 **SEC. 8. STUDY.**

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

11 **SEC. 9. QUALIFIED ORGAN PROCUREMENT ORGANIZA-**
12 **TIONS.**

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

Passed the House of Representatives March 24,
2004.

Attest:

JEFF TRANDAHL,

Clerk.