

108TH CONGRESS
2D SESSION

H. R. 3926

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 10, 2004

Mr. BILIRAKIS (for himself, Mr. BROWN of Ohio, Mr. BARTON of Texas, Mr. DINGELL, Mr. UPTON, Mr. WAXMAN, Mr. BURR, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Organ Donation and
5 Recovery Improvement Act”.

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

7 (a) PUBLIC AWARENESS OF NEED FOR ORGAN DO-
8 NATION.—It is the sense of Congress that the Federal
9 Government should carry out programs to educate the

1 public with respect to organ donation, including the need
 2 to provide for an adequate rate of such donations.

3 (b) FAMILY DISCUSSIONS OF ORGAN DONATIONS.—
 4 Congress recognizes the importance of families pledging
 5 to each other to share their lives as organ and tissue do-
 6 nors and acknowledges the importance of discussing organ
 7 and tissue donation as a family.

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

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

12 (2) acknowledges the advances in medical tech-
 13 nology that have enabled organ transplantation with
 14 organs donated by living individuals to become a via-
 15 ble treatment option for an increasing number of pa-
 16 tients.

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

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

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

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

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

12 “(2) providing for the reimbursement of such
13 incidental nonmedical expenses that are so incurred
14 as the Secretary determines by regulation to be ap-
15 propriate.

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

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

22 “(1) the term ‘donating individuals’ as includ-
23 ing individuals who in good faith incur qualifying ex-
24 penses toward the intended donation of an organ but
25 with respect to whom, for such reasons as the Sec-

1 retary determines to be appropriate, no donation of
2 the organ occurs; and

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

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

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

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

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

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

23 “(1) The term ‘donating individuals’ has the
24 meaning indicated for such term in subsection
25 (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).

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
5 purpose of carrying out this section, there is authorized
6 to be appropriated \$5,000,000 for each of the fiscal years
7 2005 through 2009.”.

8 SEC. 4. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.
9

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

13 "SEC. 377A. PUBLIC AWARENESS; STUDIES AND DEM-
14 ONSTRATIONS.

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

21 “(b) STUDIES AND DEMONSTRATIONS.—The Sec-
22 retary may make peer-reviewed grants to, or enter into
23 peer-reviewed contracts with, public and nonprofit private
24 entities for the purpose of carrying out studies and dem-

1 onstration projects to increase organ donation and recov-
2 ery rates, including living donation.

3 “(c) GRANTS TO STATES.—

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

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

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

14 “(B) establish yearly benchmarks for im-
15 provement in organ donation rates in the State;
16 and

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

22 “(3) USE OF FUNDS.—Funds received under
23 this subsection may be used by the State, or in part-
24 nership with other public agencies or private sector
25 institutions, for education and awareness efforts, in-

1 formation dissemination, activities pertaining to the
2 State donor registry, and other innovative donation
3 specific initiatives, including living donation.

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

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

20 **“SEC. 377B. GRANTS REGARDING HOSPITAL ORGAN DONA-**
21 **TION COORDINATORS.**

22 “(a) AUTHORITY.—

23 “(1) IN GENERAL.—The Secretary may award
24 grants to qualified organ procurement organizations
25 and hospitals under section 371 to establish pro-

1 grams coordinating organ donation activities of eligi-
2 ble hospitals and qualified organ procurement orga-
3 nizations under section 371. Such activities shall be
4 coordinated to increase the rate of organ donations
5 for such hospitals.

6 “(2) ELIGIBLE HOSPITAL.—For purposes of
7 this section, the term ‘eligible hospital’ means a hos-
8 pital that performs significant trauma care, or a
9 hospital or consortium of hospitals that serves a
10 population base of not fewer than 200,000 individ-
11 uals.

12 “(b) ADMINISTRATION OF COORDINATION PRO-
13 GRAM.—A condition for the receipt of a grant under sub-
14 section (a) is that the applicant involved agree that the
15 program under such subsection will be carried out joint-
16 ly—

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

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

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

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

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

7 “(3) collaboratively design and implement an
8 appropriate data collection process to provide ongoing
9 feedback to hospital and organ procurement or-
10 ganization leadership on project progress and re-
11 sults.

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

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

22 “(f) MATCHING REQUIREMENT.—The Secretary may
23 not award a grant to a qualifying organ donation entity
24 under this section unless such entity agrees that, with re-
25 spect to costs to be incurred by the entity in carrying out

1 activities for which the grant was awarded, the entity shall
 2 contribute (directly or through donations from public or
 3 private entities) non-Federal contributions in cash or in
 4 kind, in an amount equal to not less than 30 percent of
 5 the amount of the grant awarded to such entity.

6 “(g) FUNDING.—For the purpose of carrying out this
 7 section, there are authorized to be appropriated
 8 \$3,000,000 for fiscal year 2005, and such sums as may
 9 be necessary for each of fiscal years 2006 through 2009.”.

10 **SEC. 5. STUDIES RELATING TO ORGAN DONATION AND THE**
 11 **RECOVERY, PRESERVATION, AND TRANSPOR-**
 12 **TATION OF ORGANS.**

13 Part H of title III of the Public Health Service Act
 14 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
 15 tion 377B, as added by section 4, the following:

16 **“SEC. 377C. STUDIES RELATING TO ORGAN DONATION AND**
 17 **THE RECOVERY, PRESERVATION, AND TRANS-**
 18 **PORTATION OF ORGANS.**

19 “(a) DEVELOPMENT OF SUPPORTIVE INFORMA-
 20 TION.—The Secretary, acting through the Director of the
 21 Agency for Healthcare Research and Quality, shall develop
 22 scientific evidence in support of efforts to increase organ
 23 donation and improve the recovery, preservation, and
 24 transportation of organs.

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

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

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

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

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

22 “(c) RESEARCH AND DISSEMINATION.—The Sec-
23 retary, acting through the Director of the Agency for
24 Healthcare Research and Quality, as appropriate, shall

1 provide support for research and dissemination of find-
 2 ings, to—

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

5 “(2) apply information technology and tele-
 6 communications to support the clinical operations of
 7 organ procurement organizations;

8 “(3) enhance the skill levels of the organ pro-
 9 curement workforce in undertaking quality improve-
 10 ment activities; and

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

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

18 **SEC. 6. REPORT RELATING TO ORGAN DONATION AND THE**
 19 **RECOVERY, PRESERVATION, AND TRANSPOR-**
 20 **TATION OF ORGANS.**

21 Part H of title III of the Public Health Service Act
 22 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
 23 tion 377C, as added by section 5, the following:

1 **“SEC. 377D. REPORT RELATING TO ORGAN DONATION AND**
2 **THE RECOVERY, PRESERVATION, AND TRANS-**
3 **PORTATION OF ORGANS.**

4 “(a) IN GENERAL.—Not later than December 31,
5 2005, and every 2 years thereafter, the Secretary shall re-
6 port to the appropriate committees of Congress on the ac-
7 tivities of the Department carried out pursuant to this
8 part, including an evaluation describing the extent to
9 which the activities have affected the rate of organ dona-
10 tion and recovery.

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

13 “(1) evaluate the effectiveness of activities,
14 identify effective activities, and disseminate such
15 findings with respect to organ donation and recov-
16 ery;

17 “(2) assess organ donation and recovery activi-
18 ties that are recently completed, ongoing, or
19 planned; and

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

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

24 “(1) An evaluation of the organ donation prac-
25 tices of organ procurement organizations, States,
26 other countries, and other appropriate organizations

1 including an examination across all populations, in-
2 cluding those with low organ donation rates, of—

3 “(A) existing barriers to organ donation;
4 and

5 “(B) the most effective donation and re-
6 covery practices.

7 “(2) An evaluation of living donation practices
8 and procedures. Such evaluation shall include an as-
9 sessment of issues relating to informed consent and
10 the health risks associated with living donation (in-
11 cluding possible reduction of long-term effects).

12 “(3) An evaluation of—

13 “(A) federally supported or conducted
14 organ donation efforts and policies, as well as
15 federally supported or conducted basic, clinical,
16 and health services research (including research
17 on preservation techniques and organ rejection
18 and compatibility); and

19 “(B) the coordination of such efforts
20 across relevant agencies within the Department
21 and throughout the Federal Government.

22 “(4) An evaluation of the costs and benefits of
23 State donor registries, including the status of exist-
24 ing State donor registries, the effect of State donor
25 registries on organ donation rates, issues relating to

1 consent, and recommendations regarding improving
2 the effectiveness of State donor registries in increas-
3 ing overall organ donation rates.

4 “(5) A plan to improve federally supported or
5 conducted organ donation and recovery activities, in-
6 cluding, when appropriate, the establishment of
7 baselines and benchmarks to measure overall out-
8 comes of these programs. Such plan shall provide for
9 the ongoing coordination of federally supported or
10 conducted organ donation and research activities.”.

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

12 Part H of title III of the Public Health Service Act
13 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
14 tion 371 the following:

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

16 “The Secretary may establish and maintain mecha-
17 nisms to evaluate the long-term effects associated with liv-
18 ing organ donations by individuals who have served as liv-
19 ing donors.”.

20 **SEC. 8. STUDY.**

21 Not later than December 31, 2004, the Secretary of
22 Health and Human Services, in consultation with appro-
23 priate entities, including advocacy groups representing
24 those populations that are likely to be disproportionately
25 affected by proposals to increase cadaveric donation, shall

1 submit to the appropriate committees of Congress a report
2 that evaluates the ethical implications of such proposals.

3 **SEC. 9. QUALIFIED ORGAN PROCUREMENT ORGANIZA-**
4 **TIONS.**

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

○