

108TH CONGRESS
1ST SESSION

S. 573

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

IN THE SENATE OF THE UNITED STATES

MARCH 6, 2003

Mr. FRIST (for himself, Mr. DODD, and Mr. ENZI) introduced the following
bill; which was read twice and referred to the Committee on Health, Edu-
cation, Labor, and Pensions

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”.

1 **TITLE I—ORGAN DONATION AND**
2 **RECOVERY**

3 **SEC. 101. INTERAGENCY TASK FORCE ON ORGAN DONA-**
4 **TION.**

5 Part H of title III of the Public Health Service Act
6 (42 U.S.C. 273 et seq.) is amended—

7 (1) by redesignating section 378 (42 U.S.C.
8 274g) as section 378E; and

9 (2) by inserting after section 377 (42 U.S.C.
10 274f) the following:

11 **“SEC. 378. INTER-AGENCY TASK FORCE ON ORGAN DONA-**
12 **TION AND RESEARCH.**

13 “(a) IN GENERAL.—The Secretary shall establish an
14 inter-agency task force on organ donation and research
15 (referred to in this section as the ‘task force’) to improve
16 the coordination and evaluation of—

17 “(1) federally supported or conducted organ do-
18 nation efforts and policies; and

19 “(2) federally supported or conducted basic,
20 clinical and health services research (including re-
21 search on preservation techniques and organ rejec-
22 tion and compatibility).

23 “(b) COMPOSITION.—

24 “(1) IN GENERAL.—The task force shall be
25 composed of—

1 “(A) the Surgeon General, who shall serve
2 as the chairperson; and

3 “(B) representatives to be appointed by
4 the Secretary from relevant agencies within the
5 Department of Health and Human Services (in-
6 cluding the Health Resources and Services Ad-
7 ministration, Centers for Medicare & Medicaid
8 Services, National Institutes of Health, and
9 Agency for Healthcare Research and Quality).

10 “(2) OTHER EX OFFICIO MEMBERS.—The Sec-
11 retary shall invite the following individuals to serve
12 as ex officio members of the task force:

13 “(A) A representative from the Depart-
14 ment of Transportation.

15 “(B) A representative from the Depart-
16 ment of Defense.

17 “(C) A representative from the Depart-
18 ment of Veterans Affairs.

19 “(D) A representative from the Office of
20 Personnel Management.

21 “(E) A physician representative from the
22 board of directors of the Organ Procurement
23 and Transplantation Network.

1 “(F) Representatives of other Federal
2 agencies or departments as determined to be
3 appropriate by the Secretary.

4 “(c) ANNUAL REPORT.—In addition to activities car-
5 ried out under subsection (a), the task force shall support
6 the development of the annual report under section
7 378D(c).

8 “(d) TERMINATION.—The task force may be termi-
9 nated at the discretion of the Secretary following the com-
10 pletion of at least 2 annual reports under section 378D(c).
11 Upon such termination, the Secretary shall provide for the
12 on-going coordination of federally supported or conducted
13 organ donation and research activities.”.

14 **SEC. 102. DEMONSTRATION PROJECTS, EDUCATION, AND**
15 **PUBLIC AWARENESS.**

16 Part H of title III of the Public Health Service Act
17 (42 U.S.C 273 et seq.) is amended by inserting after sec-
18 tion 378, as added by section 101, the following:

19 **“SEC. 378A. DEMONSTRATION PROJECTS, EDUCATION, AND**
20 **PUBLIC AWARENESS.**

21 “(a) GRANTS TO INCREASE DONATION RATES.—The
22 Secretary shall award peer-reviewed grants to public and
23 non-profit private entities, including States, to carry out
24 studies and demonstration projects to increase organ do-
25 nation and recovery rates, including living donation.

1 “(b) ORGAN DONATION PUBLIC AWARENESS PRO-
2 GRAM.—The Secretary shall establish a public education
3 program in cooperation with existing national public
4 awareness campaigns to increase awareness about organ
5 donation and the need to provide for an adequate rate of
6 such donations.

7 “(c) DEVELOPMENT OF CURRICULA AND OTHER
8 EDUCATION ACTIVITIES.—

9 “(1) IN GENERAL.—The Secretary, in coordina-
10 tion with the Organ Procurement and Transplan-
11 tation Network and other appropriate organizations,
12 shall support the development and dissemination of
13 model curricula to train health care professionals
14 and other appropriate professionals (including reli-
15 gious leaders in the community, funeral directors,
16 and law enforcement officials) in issues surrounding
17 organ donation, including methods to approach pa-
18 tients and their families, cultural sensitivities, and
19 other relevant issues.

20 “(2) HEALTH CARE PROFESSIONALS.—For pur-
21 poses of subparagraph (A), the term ‘health care
22 professionals’ includes—

23 “(A) medical students, residents and fel-
24 lows, attending physicians (through continuing
25 medical education courses and other methods),

1 nurses, social workers, and other allied health
2 professionals;

3 “(B) hospital- or other health care-facility
4 based chaplains; and

5 “(C) emergency medical personnel.

6 “(d) LIMITED DEMONSTRATION PROJECTS.—

7 “(1) REPORTS.—Not later than 1 year after the
8 date of enactment of this section, the Secretary shall
9 prepare and submit to the appropriate committees of
10 Congress a report evaluating the ethical implications
11 of proposals for demonstration projects to increase
12 cadaveric donation.

13 “(2) AUTHORITY.—Notwithstanding section
14 301 of the National Organ Transplant Act (42
15 U.S.C. 274e), upon the submission of and consistent
16 with the report by the Secretary under paragraph
17 (1), the Secretary may conduct up to 3 demonstra-
18 tion projects to increase cadaveric donation.

19 “(3) DURATION.—Each project shall last no
20 more than 3 years, and shall be conducted in a lim-
21 ited number of sites or areas.

22 “(4) REVIEW.—The Secretary shall provide for
23 the ongoing ethical review and evaluation of such
24 projects to ensure that such projects are adminis-
25 tered effectively as possible and in accordance with

1 the stated purpose of this subsection under para-
2 graph (2).

3 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
4 is authorized to be appropriated to carry out this section,
5 \$5,000,000 for fiscal year 2004, and such sums as may
6 be necessary for each of the fiscal years 2005 through
7 2008.

8 **“SEC. 378B. GRANTS REGARDING HOSPITAL ORGAN DONA-
9 TION COORDINATORS.**

10 “(a) AUTHORITY.—

11 “(1) IN GENERAL.—The Secretary may award
12 grants to qualified organ procurement organizations
13 under section 371 to establish programs coordi-
14 nating organ donation activities of eligible hospitals
15 and qualified organ procurement organizations
16 under section 371. Such activities shall be coordi-
17 nated to increase the rate of organ donations for
18 such hospitals.

19 “(2) ELIGIBLE HOSPITAL.—For purposes of
20 this section, an eligible hospital is a hospital that
21 performs significant trauma care, or a hospital or
22 consortium of hospitals that serves a population base
23 of not fewer than 200,000 individuals.

24 “(b) ADMINISTRATION OF COORDINATION PRO-
25 GRAM.—A condition for the receipt of a grant under sub-

1 section (a) is that the applicant involved agree that the
2 program under such subsection will be carried out joint-
3 ly—

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

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

9 “(c) EVALUATIONS.—Within 3 years after the award
10 of grants under this section, the Secretary shall ensure
11 an evaluation of programs carried out pursuant to sub-
12 section (a) in order to determine the extent to which the
13 programs have increased the rate of organ donation for
14 the eligible hospitals involved. Such evaluation shall in-
15 clude recommendations on whether the program should be
16 expanded to include other grantees, such as hospitals.

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

1 “(e) FUNDING.—For the purpose of carrying out this
 2 section, there are authorized to be appropriated
 3 \$3,000,000 for fiscal year 2004, and such sums as may
 4 be necessary for each of fiscal years 2005 through 2008.”.

5 **SEC. 103. STUDIES RELATING TO ORGAN DONATION AND**
 6 **THE RECOVERY, PRESERVATION, AND TRANS-**
 7 **PORTATION OF ORGANS.**

8 Part H of title III of the Public Health Service Act
 9 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
 10 tion 378B, as added by section 102, the following:

11 **“SEC. 378C. STUDIES RELATING TO ORGAN DONATION AND**
 12 **THE RECOVERY, PRESERVATION, AND TRANS-**
 13 **PORTATION OF ORGANS.**

14 “(a) DEVELOPMENT OF SUPPORTIVE INFORMA-
 15 TION.—The Secretary, acting through the Administrator
 16 of the Health Resources and Services Administration and
 17 the Director of the Agency for Healthcare Research and
 18 Quality shall develop scientific evidence in support of ef-
 19 forts to increase organ donation and improve the recovery,
 20 preservation, and transportation of organs.

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

23 “(1) conduct or support evaluation research to
 24 determine whether interventions, technologies, or

1 other activities improve the effectiveness, efficiency,
2 or quality of existing organ donation practice;

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

8 “(3) ensure that scientific evidence of the re-
9 search and other activities undertaken under this
10 section is readily accessible by the organ procure-
11 ment workforce; and

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

18 “(c) RESEARCH, DEMONSTRATIONS, AND TRAIN-
19 ING.—The Secretary, acting through the Administrator of
20 the Health Resources and Services Administration and the
21 Director of the Agency for Healthcare Research and Qual-
22 ity, as appropriate, shall provide support for research,
23 demonstrations, and training as appropriate, to—

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

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

4 “(3) enhance the skill levels of the organ pro-
5 curement workforce in undertaking quality improve-
6 ment activities; and

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

9 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
10 purpose of carrying out this section, there are authorized
11 to be appropriated \$5,000,000 for fiscal year 2004, and
12 such sums as may be necessary for each of fiscal years
13 2005 through 2008.”.

14 **SEC. 104. REPORTS.**

15 Part H of title III of the Public Health Service Act
16 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
17 tion 378C, as added by section 103, the following:

18 **“SEC. 378D. REPORTS.**

19 “(a) IOM REPORT ON BEST PRACTICES.—

20 “(1) IN GENERAL.—The Secretary shall enter
21 into a contract with the Institute of Medicine to con-
22 duct an evaluation of the organ donation practices of
23 organ procurement organizations, States, other
24 countries, and other appropriate organizations.

1 “(2) CONSIDERATIONS.—In conducting the
2 evaluation under paragraph (1), the Institute of
3 Medicine shall examine—

4 “(A) existing barriers to organ donation,
5 including among minority populations; and

6 “(B) best donation and recovery practices,
7 including—

8 “(i) mandated choice and presumed
9 consent;

10 “(ii) organ procurement organization
11 and provider consent practices (including
12 consent best practices);

13 “(iii) the efficacy and reach of exist-
14 ing State routine notification laws with re-
15 spect to organ procurement organizations;

16 “(iv) the impact of requests for con-
17 sent in States where registry registration
18 constitutes express consent under State
19 law; and

20 “(v) recommendations with respect to
21 achieving higher donation rates, including
22 among minority populations.

23 “(3) REPORT.—Not later than 18 months after
24 the date of enactment of this section, the Institute
25 of Medicine shall submit to the Secretary a report

1 concerning the evaluation conducted under this sub-
2 section. Such report shall include recommendations
3 for administrative actions and, if necessary, legisla-
4 tion in order to replicate the best practices identified
5 in the evaluation and to otherwise increase organ do-
6 nation and recovery rates.

7 “(b) IOM REPORT ON LIVING DONATIONS.—

8 “(1) IN GENERAL.—The Secretary shall enter
9 into a contract with the Institute of Medicine to con-
10 duct an evaluation of living donation practices and
11 procedures. Such evaluation shall include, but is not
12 limited to an assessment of issues relating to in-
13 formed consent and the health risks associated with
14 living donation (including possible reduction of long-
15 term effects).

16 “(2) REPORT.—Not later than 18 months after
17 the date of enactment of this section, the Institute
18 of Medicine shall submit to the Secretary a report
19 concerning the evaluation conducted under this sub-
20 section.

21 “(c) REPORT ON DONATION AND RECOVERY ACTIVI-
22 TIES.—

23 “(1) IN GENERAL.—The Secretary as part of
24 the report specified in 274d shall submit an evalua-
25 tion concerning federally supported or conducted

1 organ donation and recovery activities, including do-
2 nation and recovery activities evaluated or conducted
3 under the amendments made by the Organ Donation
4 and Recovery Improvement Act to increase organ
5 donation and recovery rates.

6 “(2) REQUIREMENTS.—To the extent prac-
7 ticable, each evaluation submitted under paragraph
8 (1) shall—

9 “(A) evaluate the effectiveness of activities,
10 identify best practices, and make recommenda-
11 tions regarding the adoption of best practices
12 with respect to organ donation and recovery;
13 and

14 “(B) assess organ donation and recovery
15 activities that are recently completed, ongoing,
16 or planned.”.

17 **SEC. 105. TECHNICAL AMENDMENT CONCERNING ORGAN**
18 **PURCHASES.**

19 Section 301(c)(2) of the National Organ Transplant
20 Act (42 U.S.C. 274e(c)(2)) is amended by adding at the
21 end the following: “Such term does not include familial,
22 emotional, psychological, or physical benefit to an organ
23 donor, recipient, or any other party to an organ donation
24 event.”.

1 **TITLE II—LIVING DONATION**
 2 **EXPENSES**

3 **SEC. 201. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE**
 4 **EXPENSES INCURRED TOWARD LIVING**
 5 **ORGAN DONATION.**

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

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

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

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

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

23 “(b) PREFERENCE.—The Secretary shall, in carrying
 24 out subsection (a), give preference to those individuals

1 that the Secretary determines are more likely to be other-
2 wise unable to meet such expenses.

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

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

11 “(2) the term ‘qualifying expenses’ as including
12 the expenses of having relatives or other individuals,
13 not to exceed 2, who accompany or assist the donat-
14 ing individual for purposes of subsection (a) (subject
15 to making payment for only such types of expenses
16 as are paid for donating individual).

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

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

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

6 “(3) by the recipient of the organ.

7 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
8 purpose of carrying out this section, there is authorized
9 to be appropriated \$5,000,000 for fiscal year 2004, and
10 such sums as may be necessary for each of fiscal years
11 2005 through 2008.”.

12 **TITLE III—ORGAN REGISTRIES**

13 **SEC. 301. ADVISORY COMMITTEE.**

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 371 the following:

17 **“SEC. 371A. ADVISORY COMMITTEE.**

18 “(a) IN GENERAL.—Not later than 6 months after
19 enactment, the Secretary shall establish an advisory com-
20 mittee to study existing organ donor registries and make
21 recommendations to Congress regarding the costs, bene-
22 fits, and expansion of such registries.

23 “(b) MEMBERSHIP.—The committee shall be com-
24 posed of 10 members of whom—

1 “(1) at least 1 member shall be a physician
2 with experience performing transplants;

3 “(2) at least 1 member shall have experience in
4 organ recovery;

5 “(3) at least 1 member shall be representative
6 of an organization with experience conducting na-
7 tional awareness campaigns and donor outreach;

8 “(4) at least 1 member shall be representative
9 of a State with an existing donor registry;

10 “(5) at least 1 member shall have experience
11 with national information systems where coordina-
12 tion occurs with State-based systems; and

13 “(6) at least 1 member shall represent donor
14 families, transplant recipients, and those awaiting
15 transplantation.

16 “(c) INITIAL MEETING.—Not later than 30 days
17 after the date on which all members of the committee have
18 been appointed, the committee shall hold its first meeting.

19 “(d) MEETINGS.—The committee shall meet at the
20 call of the Chairman who shall be selected by the Sec-
21 retary.

22 “(e) COMPENSATION.—Each member of the com-
23 mittee shall not receive compensation for services provided
24 under this section.

1 “(f) TRAVEL EXPENSES.—The members of the com-
2 mittee shall be allowed travel expenses, including per diem
3 in lieu of subsistence, at rates authorized for employees
4 of agencies under subchapter I of chapter 57 of title 5,
5 United States Code, while away from their homes or reg-
6 ular places of business in the performance of services for
7 the committee.

8 “(g) ADMINISTRATIVE SUPPORT.—The Secretary
9 shall ensure that the committee is provided with adminis-
10 trative support or any other technical assistance that such
11 committee needs in carrying out its duties.

12 “(h) PERMANENT COMMITTEE.—Section 14 of the
13 Federal Advisory Committee Act shall not apply to the
14 committee established under this section.

15 “(i) REPORT.—Not later than 1 year after the date
16 on which the committee is established under subsection
17 (a), the committee shall prepare and submit to Congress
18 a report regarding the status of organ donor registries,
19 current best practices, the effect of organ donor registries
20 on organ donation rates, the merits of expanding organ
21 donor registries, issues relating to consent, the efficacy of
22 current privacy protections, potential forms of technical
23 assistance, and recommendations regarding improving the
24 effectiveness and establishing formal linkages between
25 organ donor registries.

