

107TH CONGRESS
2^D SESSION

S. 1949

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 14, 2002

Mr. FRIST (for himself, Mr. DODD, Mr. HUTCHINSON, Mr. JEFFORDS, and
Mr. ENZI) introduced the following bill; which was read twice and re-
ferred to the Committee on Health, Education, 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 378G; 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.—The task force shall be com-
24 posed of—

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

3 “(2) representatives to be appointed by the Sec-
4 retary from relevant agencies within the Department
5 of Health and Human Services (including the
6 Health Resources and Services Administration, Cen-
7 ters for Medicare & Medicaid Services, National In-
8 stitutes of Health, and Agency for Healthcare Re-
9 search and Quality);

10 “(3) a representative from the Department of
11 Transportation;

12 “(4) a representative from the Department of
13 Defense;

14 “(5) a representative from the Department of
15 Veterans Affairs;

16 “(6) a representative from the Office of Per-
17 sonnel Management; and

18 “(7) representatives of other Federal agencies
19 or departments as determined to be appropriate by
20 the Secretary.

21 “(c) ANNUAL REPORT.—In addition to activities car-
22 ried out under subsection (a), the task force shall support
23 the development of the annual report under section
24 378D(c).

1 “(d) **TERMINATION.**—The task force may be termi-
 2 nated at the discretion of the Secretary following the com-
 3 pletion of at least 2 annual reports under section 378D(e).
 4 Upon such termination, the Secretary shall provide for the
 5 on-going coordination of federally supported or conducted
 6 organ donation and research activities.”.

7 **SEC. 102. DEMONSTRATION PROJECTS, EDUCATION, AND**
 8 **PUBLIC AWARENESS.**

9 Part H of title III of the Public Health Service Act
 10 (42 U.S.C 273 et seq.) is amended by inserting after sec-
 11 tion 378, as added by section 101, the following:

12 **“SEC. 378A. DEMONSTRATION PROJECTS, EDUCATION, AND**
 13 **PUBLIC AWARENESS.**

14 “(a) **GRANTS TO INCREASE DONATION RATES.**—The
 15 Secretary shall award peer-reviewed grants to public and
 16 non-profit private entities, including States, to carry out
 17 studies and demonstration projects to increase organ do-
 18 nation and recovery rates, including living donation. Such
 19 projects may include projects to remove financial disincen-
 20 tives to organ donation and research on issues relating to
 21 presumed consent.

22 “(b) **ORGAN DONATION PUBLIC AWARENESS PRO-**
 23 **GRAM.**—The Secretary shall establish a public education
 24 program in cooperation with existing national public
 25 awareness campaigns to increase awareness about organ

1 donation and the need to provide for an adequate rate of
2 such donations.

3 “(c) DEVELOPMENT OF CURRICULA AND OTHER
4 EDUCATION ACTIVITIES.—

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

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

19 “(A) medical students, residents and fel-
20 lows, attending physicians (through continuing
21 medical education courses and other methods),
22 nurses, social workers, and other allied health
23 professionals; and

24 “(B) hospital- or other health care-facility
25 based chaplains; and

1 “(C) emergency medical personnel.

2 “(d) LIMITED DEMONSTRATION PROJECTS.—

3 “(1) IN GENERAL.—Notwithstanding section
4 301 of the National Organ Transplant Act (42
5 U.S.C. 274e), the Secretary may conduct up to 3
6 demonstration projects to examine methods to re-
7 duce economic barriers to organ donation, including
8 demonstration projects to increase cadaveric dona-
9 tion.

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

13 “(3) REVIEW.—The Secretary shall provide for
14 the ongoing ethical review and evaluation of such
15 projects to ensure that such projects are adminis-
16 tered effectively as possible and in accordance with
17 the stated purpose of this subsection under para-
18 graph (1).

19 “(4) REPORTS.—

20 “(A) COUNCIL’S REPORT.—The Presi-
21 dent’s Council on Bioethics, created under Ex-
22 ecutive Order 13237 (66 Fed. Reg. 59851; re-
23 lating to the Council’s creation), shall submit a
24 report to the Secretary evaluating the ethical
25 implications of methods to reduce economic bar-

1 riers to organ donation, including demonstra-
2 tion projects to increase cadaveric donation.

3 “(B) SECRETARY’S REPORT.—The Sec-
4 retary shall review such report submitted by the
5 Council and submit a report to the appropriate
6 committees of Congress that describes the re-
7 view provided by the Secretary under paragraph
8 (3) and evaluates the Council’s report sub-
9 mitted under this paragraph.

10 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
11 is authorized to be appropriated to carry out this section,
12 \$5,000,000 for fiscal year 2002, and such sums as may
13 be necessary for each of the fiscal years 2003 through
14 2006.

15 **“SEC. 378B. GRANTS REGARDING HOSPITAL ORGAN DONA-
16 TION COORDINATORS.**

17 “(a) AUTHORITY.—

18 “(1) IN GENERAL.—The Secretary may award
19 grants to qualified organ procurement organizations
20 under section 371 to establish programs coordi-
21 nating organ donation activities of eligible hospitals
22 and qualified organ procurement organizations
23 under section 371. Such activities shall be coordi-
24 nated to increase the rate of organ donations for
25 such hospitals.

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

6 “(b) ADMINISTRATION OF COORDINATION PRO-
7 GRAM.—A condition for the receipt of a grant under sub-
8 section (a) is that the applicant involved agree that the
9 program under such subsection will be carried out
10 jointly—

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

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

16 “(c) 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. Such evaluation shall in-
22 clude recommendations on whether the program should be
23 expanded to include other grantees, such as hospitals.

24 “(d) MATCHING REQUIREMENT.—The Secretary may
25 not award a grant to a qualifying organ donation entity

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

8 “(e) FUNDING.—For the purpose of carrying out this
 9 section, there are authorized to be appropriated
 10 \$3,000,000 for fiscal year 2002, and such sums as may
 11 be necessary for each of fiscal years 2003 through 2006.”.

12 **SEC. 103. STUDIES RELATING TO ORGAN AND TISSUE DO-**
 13 **NATION AND THE RECOVERY, PRESERVA-**
 14 **TION, AND TRANSPORTATION OF ORGANS**
 15 **AND TISSUES.**

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 378B, as added by section 102, the following:

19 **“SEC. 378C. STUDIES RELATING TO ORGAN AND TISSUE DO-**
 20 **NATION AND THE RECOVERY, PRESERVA-**
 21 **TION, AND TRANSPORTATION OF ORGANS**
 22 **AND TISSUES.**

23 “(a) DEVELOPMENT OF SUPPORTIVE INFORMA-
 24 TION.—The Secretary, acting through the Administrator
 25 of the Health Resources and Services Administration and

1 the Director of the Agency for Healthcare Research and
2 Quality shall develop scientific evidence in support of ef-
3 forts to increase organ and tissue donation and improve
4 the recovery, preservation, and transportation of organs
5 and tissues.

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

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

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

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

22 “(4) work in coordination with the appropriate
23 professional societies as well as the Organ Procure-
24 ment and Transplantation Network and other organ
25 procurement and transplantation organizations to

1 develop evidence and promote the adoption of such
2 proven practices.

3 “(c) RESEARCH, DEMONSTRATIONS, AND TRAIN-
4 ING.—The Secretary, acting through the Administrator of
5 the Health Resources and Services Administration and the
6 Director of the Agency for Healthcare Research and Qual-
7 ity, as appropriate, shall provide support for research,
8 demonstrations, and training as appropriate, to—

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

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

14 “(3) enhance the skill levels of the organ pro-
15 curement workforce in undertaking quality improve-
16 ment activities; and

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

19 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
20 purpose of carrying out this section, there are authorized
21 to be appropriated \$5,000,000 for fiscal year 2002, and
22 such sums as may be necessary for each of fiscal years
23 2003 through 2006.”.

1 **SEC. 104. REPORTS.**

2 Part H of title III of the Public Health Service Act
3 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
4 tion 378C, as added by section 103, the following:

5 **“SEC. 378D. REPORTS.**

6 “(a) IOM REPORT ON BEST PRACTICES.—

7 “(1) IN GENERAL.—The Secretary shall enter
8 into a contract with the Institute of Medicine to con-
9 duct an evaluation of the organ donation practices of
10 organ procurement organizations, States, other
11 countries, and other appropriate organizations.

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

15 “(A) existing barriers to organ donation;
16 and

17 “(B) best donation and recovery practices,
18 including—

19 “(i) mandated choice and presumed
20 consent;

21 “(ii) organ procurement organization
22 and provider consent practices (including
23 consent best practices);

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

1 “(iv) the impact of requests for con-
2 sent in States where registry registration
3 constitutes express consent under State
4 law; and

5 “(v) recommendations with respect to
6 achieving higher donation rates.

7 “(3) REPORT.—Not later than 18 months after
8 the date of enactment of this section, the Institute
9 of Medicine shall submit to the Secretary a report
10 concerning the evaluation conducted under this sub-
11 section. Such report shall include recommendations
12 for administrative actions and, if necessary, legisla-
13 tion in order to replicate the best practices identified
14 in the evaluation and to otherwise increase organ do-
15 nation and recovery rates.

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

17 “(1) IN GENERAL.—The Secretary shall enter
18 into a contract with the Institute of Medicine to con-
19 duct an evaluation of living donation practices and
20 procedures. Such evaluation shall include, but is not
21 limited to an assessment of issues relating to in-
22 formed consent and the health risks associated with
23 living donation (including possible reduction of long-
24 term effects).

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

6 “(c) REPORT ON DONATION AND RECOVERY ACTIVI-
7 TIES.—

8 “(1) IN GENERAL.—The Secretary as part of
9 the report specified in 274d shall submit an evalua-
10 tion concerning federally supported or conducted
11 organ donation and recovery activities, including do-
12 nation and recovery activities evaluated or conducted
13 under the amendments made by the Organ Donation
14 and Recovery Improvement Act to increase organ
15 donation and recovery rates.

16 “(2) REQUIREMENTS.—To the extent prac-
17 ticable, each evaluation submitted under paragraph
18 (1) shall—

19 “(A) evaluate the effectiveness of activities,
20 identify best practices, and make recommenda-
21 tions regarding the adoption of best practices
22 with respect to organ donation and recovery;
23 and

1 “(B) assess organ donation and recovery
2 activities that are recently completed, ongoing,
3 or planned.”.

4 **TITLE II—LIVING DONATION**
5 **EXPENSES**

6 **SEC. 201. REIMBURSEMENT OF TRAVEL AND SUBSISTENCE**
7 **EXPENSES INCURRED TOWARD LIVING**
8 **ORGAN DONATION.**

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

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

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

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

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

1 “(b) PREFERENCE FOR LOWER-INCOME DONORS.—
2 The Secretary shall, in carrying out subsection (a), give
3 preference to lower-income donors.

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

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

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

18 “(d) RELATIONSHIP TO PAYMENTS UNDER OTHER
19 PROGRAMS.—An award may be made under subsection (a)
20 only if the applicant involved agrees that the award will
21 not be expended to pay the qualifying expenses of a donat-
22 ing individual to the extent that payment has been made,
23 or can reasonably be expected to be made, with respect
24 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 2002, and
10 such sums as may be necessary for each of fiscal years
11 2003 through 2006.”.

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.

1 “(j) DEFINITION.—In this section, the term ‘organ
2 donor registry’ means a listing of individuals who have in-
3 dicated their desire to donate their organs and tissue upon
4 their death through driver’s license preferences or other
5 formal mechanisms.”.

6 **SEC. 302. NATIONAL LIVING DONOR REGISTRY.**

7 Part H of title III of the Public Health Service Act
8 (42 U.S.C. 273 et seq.), as amended by section 301, is
9 further amended by inserting after section 371A the fol-
10 lowing:

11 **“SEC. 371B. NATIONAL LIVING DONOR REGISTRY.**

12 “The Secretary shall by contract establish and main-
13 tain a registry of individuals who have served as living
14 organ donors for the purpose of evaluating the long-term
15 health effects associated with living organ donations.”.

16 **SEC. 303. QUALIFIED ORGAN PROCUREMENT ORGANIZA-**
17 **TIONS.**

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

○