

Calendar No. 509

106TH CONGRESS
2D SESSION

S. 2366

A BILL

To amend the Public Health Service Act to revise and extend provisions relating to the Organ Procurement and Transplantation Network.

APRIL 13, 2000

Reported with an amendment

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To amend the Public Health Service Act to revise and extend provisions relating to the Organ Procurement and Transplantation Network.

IN THE SENATE OF THE UNITED STATES

APRIL 5, 2000

Mr. FRIST (for himself, Mr. JEFFORDS, Mr. GREGG, Mr. ENZI, Mr. HUTCHINSON, Ms. COLLINS, Mr. BROWNBACK, Mr. HAGEL, Mr. SESSIONS, Mr. NICKLES, and Mr. FEINGOLD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 13, 2000

Reported by Mr. JEFFORDS, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Public Health Service Act to revise and extend provisions relating to the Organ Procurement and Transplantation Network.

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 Procurement
3 and Transplantation Network Amendments Act of 2000”.

4 **SEC. 2. ORGAN PROCUREMENT AND TRANSPLANTATION**
5 **NETWORK.**

6 (a) **IN GENERAL.**—Section 372 of the Public Health
7 Service Act (42 U.S.C. 274) is amended to read as follows:

8 **“SEC. 372. ORGAN PROCUREMENT AND TRANSPLANTATION**
9 **NETWORK.**

10 **“(a) ESTABLISHMENT OF NETWORK.—**

11 **“(1) IN GENERAL.—**An Organ Procurement
12 and Transplantation Network (in this section re-
13ferred to as the ‘Network’ or the ‘OPTN’) is estab-
14lished as a private network and shall operate under
15this section.

16 **“(2) REQUIREMENTS.—**The Network shall—

17 **“(A) in accordance with criteria developed**
18 **under subsection (c)(1)(B); include as members**
19 **of the Network qualified organ procurement or-**
20 **ganizations (as described in section 371(b));**
21 **transplant centers; and other entities that have**
22 **a demonstrated interest in the fields of organ**
23 **donation or transplantation (such members**
24 **shall be referred to in this section as ‘Network**
25 **participants’); and**

1 “(B) have a policy board (referred to in
2 this section as the ‘OPTN Board’) that meets
3 the requirements of subsection (b).

4 “(b) OPTN POLICY BOARD.—

5 “(1) COMPOSITION.—The OPTN Board shall
6 be composed of not more than 36 voting members
7 to be elected under paragraph (2) and 5 nonvoting,
8 ex officio members appointed under paragraph (3).

9 “(2) ELECTED MEMBERS.—

10 “(A) IN GENERAL.—The voting members
11 of the OPTN Board shall be elected by the
12 members of the Network described in sub-
13 section (a)(2)(A), from among the nominees
14 submitted under subparagraph (B), through a
15 fair and open process.

16 “(B) NOMINATING COMMITTEE.—The
17 nominating committee established under para-
18 graph (5) shall, prior to each election of OPTN
19 Board members under this paragraph, develop
20 a list of nominees for such election. Such list
21 shall reflect the diversity of Network members
22 described in subsection (a)(2)(A), including fac-
23 tors such as program type and size and geo-
24 graphic location. Recommendations may be sub-
25 mitted to the nominating committee by the Sec-

1 retary, the members of the Network described
2 in subsection (a)(2)(A), or the general public.

3 “(C) QUALIFICATIONS.—The OPTN Board
4 shall be composed of—

5 “(i) transplant surgeons and trans-
6 plant physicians;

7 “(ii) representatives of qualified organ
8 procurement organizations, transplant cen-
9 ters, voluntary health associations, or the
10 general public, including patients awaiting
11 a transplant or transplant recipients or in-
12 dividuals who have donated an organ, or
13 the family members of such patients, re-
14 cipients or donors; and

15 “(iii) individuals distinguished in the
16 fields of ethics, basic, clinical and health
17 services research, biostatistics, health care
18 policy, or health care economics or financ-
19 ing.

20 “(D) REPRESENTATION REQUIREMENT.—
21 The OPTN Board shall be structured to ensure
22 that—

23 “(i) at least 50 but not more than 55
24 percent of the members elected under this

1 paragraph are transplant surgeons and
2 transplant physicians; and

3 “(ii) at least 20 but not more than 25
4 percent of the members elected under this
5 paragraph are transplant candidates,
6 transplant recipients, organ donors and
7 family members of such individuals.

8 Nothing in this subparagraph shall be con-
9 strued to preclude an individual voting member
10 of the OPTN Board from being a representa-
11 tive described in each of clauses (i) and (iii) or
12 (ii) and (iii) of subparagraph (C) so long as the
13 limitation described in clause (i) of this sub-
14 paragraph is complied with.

15 “(3) APPOINTED MEMBERS.—

16 “(A) IN GENERAL.—The Secretary shall
17 appoint as ex officio, nonvoting members of the
18 OPTN Board, 1 representative from each of the
19 following:

20 “(i) The Health Resources and Serv-
21 ices Administration.

22 “(ii) The National Institutes of
23 Health.

24 “(iii) The Health Care Financing Ad-
25 ministration.

1 “(iv) The Agency for Healthcare Re-
2 search and Quality.

3 “(B) NETWORK ADMINISTRATOR.—The
4 Network Administrator shall appoint an ex offi-
5 cio nonvoting member of the OPTN Board.

6 “(4) TERMS OF ELECTED MEMBERS.—

7 “(A) IN GENERAL.—Except as provided
8 for in this paragraph, members of the OPTN
9 Board elected under paragraph (2) shall serve
10 for a term of 3 years and may be re-elected.

11 “(B) NEW MEMBERS.—To ensure the stag-
12 gered rotation of $\frac{1}{3}$ of the elected members of
13 the OPTN Board each year, the initial mem-
14 bers of the OPTN Board elected under para-
15 graph (2) shall serve for terms of 1, 2, or 3
16 years respectively as designated by the nomi-
17 nating committee.

18 “(C) TRANSITION.—Consistent with sub-
19 section (e)(3), the voting members of the
20 OPTN Board who are serving on the date of
21 enactment of the Organ Procurement and
22 Transplantation Network Amendments Act of
23 2000 may continue to serve until the expiration
24 of their terms. Upon such termination, the
25 nominating committee, in submitting nomina-

1 tions to fill such vacancies, shall ensure the
 2 staggered rotation of $\frac{1}{3}$ of the members elected
 3 under paragraph (2) every 3 years.

4 “(D) CONTRACT STATUS.—A change in the
 5 status of a contract under subsection (f), or a
 6 change in the contractor, shall not affect the
 7 terms of the members of the OPTN Board.

8 “(5) CHAIRPERSON AND COMMITTEES.—The
 9 OPTN Board shall have a chairperson, an executive
 10 committee, a nominating committee, a membership
 11 committee, and such other committees as the OPTN
 12 Board determines to be appropriate.

13 “(e) GENERAL FUNCTIONS OF THE OPTN BOARD.—

14 “(1) ESTABLISHMENT OF NETWORK POLICIES
 15 AND CRITERIA.—The OPTN Board shall—

16 “(A) after consultation with Network par-
 17 ticipants and the Network Administrator, estab-
 18 lish and carry out the policies and functions de-
 19 scribed in this section for the Network;

20 “(B) establish membership criteria for par-
 21 ticipating in the Network;

22 “(C) establish medical criteria for allo-
 23 cating organs and for listing and de-listing pa-
 24 tients on the national lists maintained under
 25 paragraph (2); and

1 ~~“(D) establish performance criteria for~~
2 ~~transplant programs.~~

3 ~~“(2) NATIONAL SYSTEM.—The OPTN Board~~
4 ~~shall maintain a national system to match organs~~
5 ~~and individuals who need organ transplants. The na-~~
6 ~~tional system shall—~~

7 ~~“(A) have 1 or more lists of individuals~~
8 ~~who are in need of organ transplants; and~~

9 ~~“(B) be operated in accordance with Net-~~
10 ~~work policies and criteria established under~~
11 ~~paragraph (1).~~

12 ~~“(3) NO FIDUCIARY RESPONSIBILITY.—The~~
13 ~~OPTN Board shall have no voting member who has~~
14 ~~any fiduciary responsibility to the entity that holds~~
15 ~~the contract provided for under this section.~~

16 ~~“(4) OPTN BOARD REQUIREMENTS.—The~~
17 ~~OPTN Board shall cooperate with the Network Ad-~~
18 ~~ministrator to ensure compliance with the require-~~
19 ~~ments of this section including the contract entered~~
20 ~~into under subsection (f).~~

21 ~~“(d) ORGAN TRANSPLANT POLICY.—The OPTN~~
22 ~~Board shall establish organ transplant policies, including~~
23 ~~organ allocation policies for potential organ recipients and~~
24 ~~policies that affect patient outcomes. Such policies shall—~~

25 ~~“(1) be based on sound medical principles;~~

1 “(2) be based on valid scientific data;

2 “(3) be equitable;

3 “(4) seek to achieve the best use of donated or-
4 gans;

5 “(5) be designed to avoid wasting organs; to
6 avoid futile transplants and reduce the risk of re-
7 transplantation; to promote patient access to trans-
8 plantation; and to promote the efficient management
9 of organ placement;

10 “(6) be specific for each organ type or combina-
11 tion of organ types;

12 “(7) be based on standardized medical criteria
13 for listing and de-listing candidates from organ
14 transplant waiting lists;

15 “(8) determine priority rankings (within cat-
16 egories as appropriate) for candidates who are medi-
17 cally suitable for transplantation; such rankings
18 shall be based on standardized medical criteria and
19 ordered according to medical urgency and medical
20 appropriateness;

21 “(9) seek distribution of organs as appropriate
22 based on paragraphs (1) through (8);

23 “(10) develop and apply appropriate perform-
24 ance indicators; including patient-focused indicators;
25 to assess transplant program performance and re-

1 duce inter-transplant program variance to improve
2 program performance; and

3 “(11) seek to reduce disparities in transplan-
4 tation resulting from socioeconomic status, race, eth-
5 nicity, or being medically underserved.

6 “(e) ENFORCEMENT OF ORGAN TRANSPLANT POL-
7 ICY.—

8 “(1) IN GENERAL.—

9 “(A) PROPOSED POLICY.—This paragraph
10 shall apply to any proposed transplant policy
11 that is developed by the OPTN Board that the
12 Board or the Secretary determines should be
13 enforced under this section or under section
14 1138 of the Social Security Act.

15 “(B) SUBMISSION OF POLICY.—Not later
16 than 60 days prior to the implementation of a
17 proposed policy described in subparagraph (A),
18 the OPTN Board shall submit such proposed
19 policy to the Secretary.

20 “(C) PUBLICATION.—Upon receipt of a
21 proposed policy under subparagraph (B), the
22 Secretary shall publish the policy in the Federal
23 Register for a 60-day public comment period.

24 “(D) ACTION BY SECRETARY.—Not later
25 than 90 days after receipt of a proposed policy

1 under subparagraph (B), the Secretary shall
 2 consider public comments received under sub-
 3 paragraph (C) and shall—

4 “(i) notify the OPTN Board that the
 5 policy is consistent with this section and
 6 therefore enforceable; or

7 “(ii) notify the OPTN Board that the
 8 policy is inconsistent with this section and
 9 direct the Board to reconsider and revise
 10 the policy consistent with the recommenda-
 11 tions of the Secretary.

12 “(E) RECONSIDERATION.—

13 “(i) IN GENERAL.—Not later than 30
 14 days after receiving a notice from the Sec-
 15 retary under subparagraph (D)(ii), the
 16 OPTN Board shall reaffirm the proposed
 17 policy or revise and submit such revised
 18 policy to the Secretary.

19 “(ii) ACTION BY SECRETARY.—Not
 20 later than 30 days after receiving a revised
 21 policy under clause (i), the Secretary
 22 shall—

23 “(I) notify the OPTN Board that
 24 the revised policy is consistent with

1 this section and therefore enforceable;
2 or

3 “(H) notify the OPTN Board
4 that the revised policy is inconsistent
5 with this section and submit the re-
6 vised policy, with the comments and
7 proposed revisions of the Secretary, to
8 the Scientific Advisory Committee on
9 Organ Transplantation (referred to in
10 this subsection as the ‘Committee’) es-
11 tablished under paragraph (2).

12 “(iii) ACTION BY COMMITTEE.—Not
13 later than 30 days after the submission of
14 a revised policy to the Committee under
15 clause (ii), the Committee may, by a ma-
16 jority vote, disapprove the comments or re-
17 vision of the Secretary. If the Committee
18 disapproves such comments or revisions,
19 the revised policy shall not take effect until
20 a majority of the Committee approves the
21 policy or the revisions to such policy.

22 “(2) SCIENTIFIC ADVISORY COMMITTEE ON
23 ORGAN TRANSPLANTATION.—

24 “(A) ESTABLISHMENT.—The Secretary
25 shall establish an advisory committee to be

1 known as the Scientific Advisory Committee on
2 Organ Transplantation. Consistent with the re-
3 quirements of sections 5 and 10 of the Federal
4 Advisory Committee Act—

5 “(i) the deliberations of the Com-
6 mittee shall not be inappropriately influ-
7 enced by the Secretary or by any special
8 interest and shall only be the result of the
9 independent judgment of the Committee;
10 and

11 “(ii) the meetings of the Committee
12 shall be open to the public; advance notice
13 of meetings shall be published in the Fed-
14 eral Register, and records or minutes of
15 meetings shall be made available to the
16 public.

17 “(B) DUTIES.—The Committee shall make
18 recommendations with respect to policy matters
19 related to reviews conducted under paragraph
20 (1)(E)(ii)(II).

21 “(C) MEMBERSHIP.—The Committee shall
22 be composed of 15 members, of which—

23 “(i) five members shall be appointed
24 by the Secretary from nominations sub-

1 mitted by the OPTN Board under sub-
2 paragraph (D);

3 “~~(ii)~~ five members shall be appointed
4 by the Secretary from nominations sub-
5 mitted by the Institute of Medicine under
6 subparagraph (D); and

7 “~~(iii)~~ five members shall be appointed
8 by the Secretary.

9 “~~(D)~~ NOMINATIONS.—The OPTN Board
10 and the Institute of Medicine shall each nomi-
11 nate, in an independent manner, 5 qualified in-
12 dividuals to serve on the Committee.

13 “~~(E)~~ QUALIFICATIONS.—In appointing in-
14 dividuals to serve on the Committee under sub-
15 paragraph (C), the Secretary shall ensure
16 that—

17 “~~(i)~~ nine members are transplant phy-
18 sicians or transplant surgeons of whom—

19 “~~(I)~~ 3 shall be selected from the
20 nominations submitted by the OPTN
21 Board; and

22 “~~(II)~~ 3 shall be selected from the
23 nominations submitted by the Insti-
24 tute of Medicine; and

1 “(ii) the remaining members are indi-
2 viduals who are—

3 “(I) distinguished in the fields of
4 ethics, basic, clinical or health services
5 research, biostatistics, or health care
6 policy, economics or financing; or

7 “(II) transplant candidates,
8 transplant recipients, organ donors or
9 family members of such individuals.

10 “(F) EXPERTS.—The Committee shall
11 seek advice from appropriate experts, as need-
12 ed, to evaluate the proposed policy and revisions
13 under review.

14 “(G) CHAIRPERSON.—The members of the
15 Committee shall elect a member to serve as the
16 chairperson of the Committee.

17 “(H) TERMS.—Members of the Committee
18 shall serve for a term of 5 years. Vacancies
19 shall be filled in the same manner as the origi-
20 nal appointment was made.

21 “(f) NETWORK ADMINISTRATION AND OPERATION.—
22 The Secretary shall contract with a nonprofit private enti-
23 ty (referred to in this section as the ‘Network Adminis-
24 trator’) for the administration and operation of the Net-
25 work. The Network Administrator shall administer and

1 operate the OPTN Board in accordance with subsection
2 (b). The Network Administrator shall, pursuant to the
3 policies and criteria established by the OPTN Board—

4 “(1) maintain and operate a national system as
5 established by the OPTN Board to match organs
6 and individuals who need organ transplants;

7 “(2) operate in accordance with medical criteria
8 established by the OPTN Board, and administer the
9 national system established under subsection (c)(2);

10 “(3) maintain ~~1~~ or more lists of individuals who
11 need organ transplants as provided for under sub-
12 section (c)(2)(A);

13 “(4) maintain a 24-hour communication service
14 to facilitate matching organs with individuals in-
15 eluded on the list or lists;

16 “(5) assist organ procurement organizations in
17 obtaining and distributing organs in accordance with
18 the policies established by the OPTN Board;

19 “(6) adopt and use standards of quality for the
20 acquisition and transportation of donated organs, in-
21 cluding standards regarding the transmission of in-
22 fectious diseases;

23 “(7) prepare and distribute, on a regionalized
24 basis (and, to the extent practicable, among regions
25 or on a national basis), samples of blood sera from

1 individuals who are included on the list in order to
 2 facilitate matching the compatibility of such individ-
 3 uals with organ donors;

4 “(8) coordinate, as appropriate, the transpor-
 5 tation of organs from organ procurement organiza-
 6 tions to transplant centers;

7 “(9) provide information to physicians, health
 8 care professionals, and the general public regarding
 9 organ donation;

10 “(10) carry out studies and demonstration
 11 projects for the purpose of improving procedures for
 12 organ procurement and allocation; and

13 “(11) work actively with organ procurement or-
 14 ganizations, transplant centers, health care pro-
 15 viders, and the public to increase the supply of do-
 16 nated organs.

17 “(g) DATA COLLECTION, ANALYSIS AND DISTRIBUTION.—
 18 TION.—

19 “(1) IN GENERAL.—The Network Adminis-
 20 trator shall analyze, maintain, verify, make available
 21 and publish timely data to the extent necessary to—

22 “(A) enable the OPTN Board to fulfill its
 23 responsibilities under this section;

1 “(B) assess the compliance of members of
2 the Network with performance and other cri-
3 teria developed pursuant to subsection (c)(1);

4 “(C) evaluate the quality of care provided
5 to transplant candidates and patients generally
6 and in an individual program;

7 “(D) provide data needed by the Scientific
8 Registry maintained pursuant to section 373;

9 “(E) provide transplant candidates and pa-
10 tients, physicians and others with information
11 needed to evaluate or select a transplant pro-
12 gram;

13 “(F) provide a member of the Network
14 with data about the member, including results
15 of analysis or other processing of data originally
16 supplied by the member;

17 “(G) enable the OPTN Board, the Net-
18 work Administrator and the Secretary to fulfill
19 respective enforcement and oversight respon-
20 sibilities under subsections (j) and (k); and

21 “(H) comply with the requirements under
22 subsection (l).

23 “(2) TYPES OF DATA.—Data provided under
24 paragraph (1) shall include—

1 “(A) data on transplant candidates, trans-
2 plant recipients, organ donors, donated organs,
3 and transplant programs; and

4 “(B) as appropriate, data, graft- and pa-
5 tient-survival rates (actual and adjusted to re-
6 flect program-specific population disease sever-
7 ity), program specific data, and aggregate data.

8 “(h) CONTRACT.—The contract under subsection (f)
9 shall—

10 “(1) be awarded through a process of competi-
11 tive bidding as determined by the Secretary; and

12 “(2) be awarded for a period of no longer than
13 5 years.

14 “(i) NETWORK MEMBERSHIP AND PATIENT REG-
15 ISTRATION FEE.—

16 “(1) IN GENERAL.—The Network Adminis-
17 trator may assess a fee, to be collected by the Net-
18 work Administrator, for membership in the Network
19 (to be known as the ‘Network membership fee’), and
20 for the listing of each potential transplant recipient
21 on the national organ matching system maintained
22 by the Network Administrator (to be known as the
23 ‘patient registration fee’), in an amount determined
24 under paragraph (2).

1 ~~“(2) AMOUNT.—~~The amounts of the fees to be
 2 assessed under paragraph (1) shall be calculated so
 3 as to be—

4 ~~“(A) reasonable and customary; and~~

5 ~~“(B) sufficient to cover the Network’s rea-~~
 6 ~~sonable costs of operation in accordance with~~
 7 ~~this section.~~

8 ~~“(3) ANNUAL RECALCULATION.—~~

9 ~~“(A) IN GENERAL.—~~The fees calculated
 10 under paragraph (2) shall be annually recal-
 11 culated, based on—

12 ~~“(i) changes in the level or cost of~~
 13 ~~contract tasks and other activities related~~
 14 ~~to organ procurement and transplantation;~~
 15 ~~and~~

16 ~~“(ii) changes in expected revenues~~
 17 ~~from contract funds, Network membership~~
 18 ~~fees and patient registration fees available~~
 19 ~~to the Network Administrator.~~

20 ~~“(B) PROCEDURE.—~~

21 ~~“(i) PROPOSAL.—~~The Network Ad-
 22 ~~ministrators shall submit to the Secretary a~~
 23 ~~written proposal for, and justification of, a~~
 24 ~~recalculated fee under subparagraph (A).~~

1 “(ii) DETERMINATION.—The proposal
2 of the Network Administrator for a recal-
3 culated fee under clause (i) shall take ef-
4 fect unless the Secretary, within 60 days of
5 receiving the proposal, provides the Net-
6 work Administrator with a written deter-
7 mination, with justification, that the pro-
8 posed fee level does not meet the require-
9 ment of subparagraph (A).

10 “(4) USE OF FEES.—

11 “(A) IN GENERAL.—All fees collected by
12 the Network Administrator under this sub-
13 section shall be available to the Network, with-
14 out fiscal year limitation, for use in carrying
15 out the functions described in subsection (f).

16 “(B) RESTRICTION.—Fees collected under
17 this subsection may not be used for any activity
18 for which contract funds may not be used under
19 this section.

20 “(5) RULE OF CONSTRUCTION.—Nothing in
21 this subsection shall be construed as prohibiting the
22 Network Administrator from collecting or accepting
23 other fees, donations or gifts or for using such other
24 fees, donations or gifts to carry out activities other

1 than those authorized under the contract under this
2 section.

3 “(j) OVERSIGHT OF NETWORK PARTICIPANTS.—

4 “(1) MONITORING.—

5 “(A) IN GENERAL.—The OPTN Board
6 and the Network Administrator shall, on an on-
7 going and periodic basis, or as requested by the
8 Secretary, monitor the operations of Network
9 participants to determine whether the partici-
10 pants are maintaining compliance with the cri-
11 teria and policies established by the OPTN
12 Board.

13 “(B) PROCEDURES.—

14 “(i) NOTICE.—In monitoring a Net-
15 work participant under subparagraph (A),
16 the OPTN Board or the Administrator—

17 “(I) shall inform the participant
18 and the Secretary upon initiating a
19 compliance review of a Network par-
20 ticipant; and

21 “(II) shall inform the participant
22 and the Secretary of any findings in-
23 dicating noncompliance by the partici-
24 pant with such criteria and policies.

1 “(ii) APPEALS.—The Network Admin-
2 istrator shall establish procedures for ap-
3 pealing noncompliance determinations.
4 Such procedures shall ensure due process
5 and shall allow for corrective action.

6 ~~“(2) PEER REVIEW PROCEEDINGS.—~~

7 “(A) IN GENERAL.—The OPTN Board
8 shall establish a peer review system and condi-
9 tions for the application of peer review require-
10 ments to ensure that members of the Network
11 comply with policies and criteria established by
12 the OPTN Board under this section. Such peer
13 review system may include prospective reviews
14 and shall be administered by the Network Ad-
15 ministrator and overseen by the OPTN Board.

16 “(B) POLICIES, REVIEW AND EVALUA-
17 TION.—As part of the peer review system estab-
18 lished under subparagraph (A), the OPTN
19 Board shall establish such policies, and the Net-
20 work Administrator shall conduct such ongoing
21 and periodic reviews and evaluations of mem-
22 bers of the Network, as necessary to ensure
23 compliance with the policies and criteria estab-
24 lished by the OPTN Board under this section.

1 “(C) EMERGING ISSUES.—As part of such
 2 peer review system established under subpara-
 3 graph (A), the OPTN Board shall establish
 4 policies to work with and direct the Network
 5 Administrator to respond to emerging issues
 6 and problems.

7 “(k) ENFORCEMENT.—

8 “(1) RECOMMENDATIONS.—The OPTN Board
 9 or the Network Administrator shall provide advice,
 10 and make recommendations for appropriate action,
 11 to the Secretary concerning the results of any re-
 12 views or evaluations that, in the opinion of the
 13 OPTN Board or the Network Administrator,
 14 indicate—

15 “(A) noncompliance by Network partici-
 16 pants with—

17 “(i) the policies or criteria established
 18 by the OPTN Board; or

19 “(ii) the operating procedures of the
 20 Network Administrator; or

21 “(B) a risk to the health of organ trans-
 22 plant patients or to public safety.

23 “(2) ENFORCEMENT BY NETWORK.—

24 “(A) IN GENERAL.—If the OPTN Board
 25 determines that one of the members of the net-

1 work has violated a requirement established by
 2 this section or by the Network, the OPTN
 3 Board may impose on the member 1 or more of
 4 the sanctions described in subparagraph (B), or
 5 may recommend that the Secretary take en-
 6 forcement action under paragraph (3).

7 “(B) TYPES OF SANCTIONS.—The sanc-
 8 tions described in this subparagraph may
 9 include—

10 “(i) the loss of any or all privileges of
 11 membership in good standing in the Net-
 12 work;

13 “(ii) the imposition upon the member
 14 of additional or more frequent reviews or
 15 evaluations under subsection (j)(1)(A), and
 16 assessments of the reasonable costs of such
 17 additional or more frequent reviews or
 18 evaluations; and

19 “(iii) such other sanctions as the Sec-
 20 retary may permit the OPTN Board to im-
 21 pose.

22 “(3) ENFORCEMENT BY THE SECRETARY.—

23 “(A) IN GENERAL.—If the Secretary, after
 24 consultation with the OPTN Board or Network
 25 Administrator, determines that a member of the

1 Network has violated a requirement established
2 by this section or a requirement of a policy that
3 is enforceable under subsection (f), the Sec-
4 retary may impose on the member 1 or more of
5 the sanctions described in subparagraph (B).

6 “(B) TYPES OF SANCTIONS.—The sanc-
7 tions described in this subparagraph shall
8 include—

9 “(i) requiring the member to follow a
10 directed plan of correction;

11 “(ii) imposing upon the member a
12 monetary assessment (to be paid to the
13 General Fund of the Treasury) in an
14 amount not to exceed \$10,000 for each
15 violation or for each day of violation;

16 “(iii) requiring the member to pay to
17 the Network Administrator the costs of on-
18 site monitoring of the member;

19 “(iv) the loss of any or all privileges
20 of membership in the Network; and

21 “(v) in cases where the violation cre-
22 ates a risk to patient health or to public
23 health, such other action as the Secretary
24 determines to be necessary.

1 “(C) PROCEDURES.—The Secretary shall
2 develop and implement procedures for the im-
3 position of sanctions under clauses (i) through (v)
4 of subparagraph (B). Such procedures shall
5 include—

6 “(i) the provision of reasonable notice
7 to the Network member and the OPTN
8 Board that the Secretary is considering
9 imposing a sanction;

10 “(ii) affording the member a reason-
11 able opportunity to be heard in response to
12 the notice;

13 “(iii) the provision of notice to the
14 member that the Secretary has decided to
15 impose a sanction; and

16 “(iv) the opportunity for the Network
17 member to appeal such sanction.

18 “(1) ANNUAL REPORT.—

19 “(1) IN GENERAL.—Not later than September
20 30 of each year, the Network Administrator shall
21 prepare and submit to the Secretary an annual re-
22 port on the performance and policies of the Network.
23 The report shall include additional items as specified
24 in the contract under this section or requested in a
25 timely manner by the Secretary.

1 “(2) REQUIREMENT OF OPTN BOARD AP-
2 PROVAL.—The OPTN Board shall review and ap-
3 prove the report required under paragraph (1) prior
4 to the submission of such report to the Secretary.

5 “(3) SUBMISSION TO CONGRESS.—

6 “(A) IN GENERAL.—Not later than De-
7 cember 31 of each year, the Secretary shall
8 transmit the report submitted under paragraph
9 (1) and the comments of the Secretary con-
10 cerning such report, to the appropriate commit-
11 tees of Congress.

12 “(B) CLARIFYING INFORMATION.—The
13 Secretary may, upon the receipt of the report
14 under paragraph (1), but prior to transmission
15 of the report to Congress under subparagraph
16 (A), request that the Network Administrator
17 submit clarifying information or an addenda as
18 needed to fulfill the requirements of this sub-
19 section.

20 “(m) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated to carry out this section,
22 such sums as may be necessary for each of fiscal years
23 2001 through 2005.”.

1 **SEC. 3. SCIENTIFIC REGISTRY.**

2 Section 373 of the Public Health Service Act (42
3 U.S.C. 274a) is amended to read as follows:

4 **“SEC. 373. SCIENTIFIC REGISTRY.**

5 “The Secretary shall by contract, develop and main-
6 tain a scientific registry of the recipients of organ trans-
7 plants. The registry shall include information, with respect
8 to organ transplant patients and transplant procedures,
9 as the Secretary determines to be necessary to an ongoing
10 evaluation of the scientific and clinical status of organ
11 transplantation.”.

12 **SEC. 4. ORGAN DONATION.**

13 Part H of title III of the Public Health Service Act
14 (42 U.S.C. 273 et seq.) is amended—

15 (1) by redesignating section 378 (42 U.S.C.
16 274g) as section 379; and

17 (2) by inserting after section 377 (42 U.S.C.
18 274f) the following:

19 **“SEC. 378. ORGAN DONATION AND RESEARCH.**

20 **“(a) INTER-AGENCY TASK FORCE ON ORGAN DONA-
21 TION AND RESEARCH.—**

22 **“(1) IN GENERAL.—**The Secretary shall estab-
23 lish an inter-agency task force on organ donation
24 and research (referred to in this section as the ‘task
25 force’) to improve the coordination and evaluation
26 of—

1 “(A) federally supported or conducted
2 organ donation efforts and policies; and

3 “(B) federally supported or conducted
4 basic, clinical and health services research (in-
5 cluding research on preservation techniques and
6 organ rejection and compatibility).

7 “(2) COMPOSITION.—The task force shall be
8 composed of—

9 “(A) the Surgeon General, who shall serve
10 as the chairperson;

11 “(B) representatives to be appointed by
12 the Secretary from relevant agencies within the
13 Department of Health and Human Services (in-
14 cluding the Health Resources and Services Ad-
15 ministration, Health Care Financing Adminis-
16 tration, National Institutes of Health, and
17 Agency for Healthcare Research and Quality);

18 “(C) a representative from the Department
19 of Transportation;

20 “(D) a representative from the Depart-
21 ment of Defense;

22 “(E) a representative from the Department
23 of Veterans Affairs;

24 “(F) a representative from the Office of
25 Personnel Management; and

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

4 “(3) ANNUAL REPORT.—In addition to activi-
5 ties carried out under paragraph (1), the task force
6 shall support the development of the annual report
7 under subsection (d)(2).

8 “(4) TERMINATION.—The task force may be
9 terminated at the discretion of the Secretary fol-
10 lowing the completion of at least 2 annual reports
11 under subsection (d). Upon such termination, the
12 Secretary shall provide for the on-going coordination
13 of federally supported or conducted organ donation
14 and research activities.

15 “(b) EDUCATION.—

16 “(1) PUBLIC EDUCATION AND AWARENESS.—
17 The Secretary shall, directly or through grants or
18 contracts, carry out a comprehensive and effective
19 national public education program to increase organ
20 donation, including living donation.

21 “(2) DEVELOPMENT OF CURRICULA AND
22 OTHER EDUCATION ACTIVITIES.—

23 “(A) IN GENERAL.—The Secretary shall
24 support the development and dissemination of
25 model curricula to train health care profes-

1 sionals and other appropriate professionals (in-
2 cluding religious leaders in the community and
3 law enforcement officials) in issues surrounding
4 organ donation, including methods to approach
5 patients and their families, cultural sensitivities,
6 and other relevant issues.

7 “(B) HEALTH CARE PROFESSIONALS.—
8 For purposes of subparagraph (A), the term
9 ‘health care professionals’ includes—

10 “(i) medical students, residents and
11 fellows, attending physicians (through con-
12 tinuing medical education courses and
13 other methods), nurses, social workers, and
14 other allied health professionals; and

15 “(ii) hospital- or other health care-fa-
16 cility based chaplains; and

17 “(iii) emergency medical personnel.

18 “(e) GRANTS.—The Secretary shall award peer-re-
19 viewed grants to public and non-profit private entities, in-
20 cluding States, to carry out studies and demonstration
21 projects to increase organ donation rates, including living
22 donation. The Secretary shall ensure that activities carried
23 out by grantees under this subsection are evaluated for
24 effectiveness and that such findings are disseminated.

25 “(d) REPORTS.—

1 “(1) IOM REPORT ON BEST PRACTICES.—

2 “(A) IN GENERAL.—The Secretary shall
3 enter into a contract with the Institute of Medi-
4 cine to conduct an evaluation of the organ do-
5 nation practices of organ procurement organiza-
6 tions, States, other countries, and other appro-
7 priate organizations that have achieved a higher
8 than average organ donation rate.

9 “(B) BARRIERS.—In conducting the eval-
10 uation under subparagraph (A), the Institute of
11 Medicine shall examine existing barriers to
12 organ donation.

13 “(C) REPORT.—Not later than 18 months
14 after the date of enactment of this section, the
15 Institute of Medicine shall submit to the Sec-
16 retary a report concerning the evaluation con-
17 ducted under this paragraph. Such report shall
18 include recommendations for administrative ac-
19 tions and, if necessary, legislation in order to
20 replicate the best practices identified in the
21 evaluation and to otherwise increase organ do-
22 nation and procurement rates.

23 “(2) ANNUAL REPORT ON DONATION.—

24 “(A) IN GENERAL.—Not later than 1 year
25 after the date on which the report is submitted

1 under paragraph (1)(C), and annually there-
2 after, the Secretary shall prepare and submit to
3 Congress a report concerning federally sup-
4 ported or conducted organ donation and pro-
5 curement activities, including donation and pro-
6 curement activities evaluated or conducted
7 under subsection (a) to increase organ dona-
8 tion.

9 “(B) REQUIREMENTS.—To the extent
10 practicable, each annual report under subpara-
11 graph (A) shall—

12 “(i) evaluate the effectiveness of ac-
13 tivities, identify best practices, and make
14 recommendations regarding broader adop-
15 tion of best practices with respect to organ
16 donation and procurement;

17 “(ii) assess organ donation and pro-
18 curement activities that are recently com-
19 pleted, current or planned.

20 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated to carry out this section,
22 \$15,000,000 for fiscal year 2001, and such sums as may
23 be necessary for each of fiscal years 2002 through 2005.”.

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Organ Procurement and*
 3 *Transplantation Network Amendments Act of 2000”.*

4 **SEC. 2. ORGAN PROCUREMENT AND TRANSPLANTATION**
 5 **NETWORK.**

6 *(a) IN GENERAL.—Section 372 of the Public Health*
 7 *Service Act (42 U.S.C. 274) is amended to read as follows:*

8 **“SEC. 372. ORGAN PROCUREMENT AND TRANSPLANTATION**
 9 **NETWORK.**

10 *“(a) ESTABLISHMENT OF NETWORK.—*

11 *“(1) IN GENERAL.—An Organ Procurement and*
 12 *Transplantation Network (in this section referred to*
 13 *as the ‘Network’ or the ‘OPTN’) is established under*
 14 *this section and shall be operated by a private non-*
 15 *profit entity as provided for in subsection (f).*

16 *“(2) REQUIREMENTS.—The Network shall—*

17 *“(A) in accordance with criteria developed*
 18 *under subsection (c)(1)(B), include as members*
 19 *of the Network qualified organ procurement or-*
 20 *ganizations (as described in section 371(b)),*
 21 *transplant centers, and other entities that have a*
 22 *demonstrated interest in the fields of organ dona-*
 23 *tion or transplantation (such members shall be*
 24 *referred to in this section as ‘Network partici-*
 25 *pants’); and*

1 “(B) have a policy board (referred to in this
2 section as the ‘OPTN Board’) that meets the re-
3 quirements of subsection (b).

4 “(b) OPTN POLICY BOARD.—

5 “(1) COMPOSITION.—The OPTN Board shall be
6 composed of not more than 36 voting members to be
7 elected under paragraph (2) and 5 nonvoting, *ex offi-*
8 *cio* members appointed under paragraph (3).

9 “(2) ELECTED MEMBERS.—

10 “(A) IN GENERAL.—The voting members of
11 the OPTN Board shall be elected by the members
12 of the Network described in subsection (a)(2)(A),
13 from among the nominees submitted under sub-
14 paragraph (B), through a fair and open process.

15 “(B) NOMINATING COMMITTEE.—The nomi-
16 nating committee established under paragraph
17 (5) shall, prior to each election of OPTN Board
18 members under this paragraph, develop a list of
19 nominees for such election. Such list shall reflect
20 the diversity of Network members described in
21 subsection (a)(2)(A), including factors such as
22 program type and size and geographic location.
23 Recommendations may be submitted to the nomi-
24 nating committee by the Secretary, the members

1 *of the Network described in subsection (a)(2)(A),*
2 *or the general public.*

3 “(C) *QUALIFICATIONS.—The OPTN Board*
4 *shall be composed of—*

5 “(i) *transplant surgeons and trans-*
6 *plant physicians;*

7 “(ii) *representatives of qualified organ*
8 *procurement organizations, transplant cen-*
9 *ters, voluntary health associations, or the*
10 *general public, including patients awaiting*
11 *a transplant or transplant recipients or in-*
12 *dividuals who have donated an organ, or*
13 *the family members of such patients, recipi-*
14 *ents or donors; and*

15 “(iii) *individuals distinguished in the*
16 *fields of ethics, basic, clinical and health*
17 *services research, biostatistics, health care*
18 *policy, or health care economics or financ-*
19 *ing.*

20 “(D) *REPRESENTATION REQUIREMENT.—*
21 *The OPTN Board shall be structured to ensure*
22 *that—*

23 “(i) *approximately 50 percent of the*
24 *members elected under this paragraph are*

1 *transplant surgeons and transplant physi-*
 2 *cians; and*

3 “*(ii) approximately 25 percent of the*
 4 *members elected under this paragraph are*
 5 *transplant candidates, transplant recipi-*
 6 *ents, organ donors and family members of*
 7 *such individuals.*

8 *Nothing in this subparagraph shall be construed*
 9 *to preclude an individual voting member of the*
 10 *OPTN Board from being a representative de-*
 11 *scribed in each of clauses (i) and (iii) or (ii) and*
 12 *(iii) of subparagraph (C) so long as the limita-*
 13 *tion described in clause (i) of this subparagraph*
 14 *is complied with.*

15 “(3) *APPOINTED MEMBERS.—*

16 “(A) *IN GENERAL.—The Secretary shall ap-*
 17 *point as ex officio, nonvoting members of the*
 18 *OPTN Board, 1 representative from each of the*
 19 *following:*

20 “(i) *The Health Resources and Services*
 21 *Administration.*

22 “(ii) *The National Institutes of Health.*

23 “(iii) *The Health Care Financing Ad-*
 24 *ministration.*

1 “(iv) *The Agency for Healthcare Re-*
2 *search and Quality.*

3 “(B) *NETWORK ADMINISTRATOR.—The Net-*
4 *work Administrator shall appoint an ex officio*
5 *nonvoting member of the OPTN Board.*

6 “(4) *TERMS OF ELECTED MEMBERS.—*

7 “(A) *IN GENERAL.—Except as provided for*
8 *in this paragraph, members of the OPTN Board*
9 *elected under paragraph (2) shall serve for a*
10 *term of 3 years and may be re-elected.*

11 “(B) *NEW MEMBERS.—To ensure the stag-*
12 *gered rotation of $\frac{1}{3}$ of the elected members of the*
13 *OPTN Board each year, the initial members of*
14 *the OPTN Board elected under paragraph (2)*
15 *shall serve for terms of 1, 2, or 3 years respec-*
16 *tively as designated by the nominating com-*
17 *mittee.*

18 “(C) *TRANSITION.—Consistent with sub-*
19 *section (c)(3), the voting members of the OPTN*
20 *Board who are serving on the date of enactment*
21 *of the Organ Procurement and Transplantation*
22 *Network Amendments Act of 2000 may continue*
23 *to serve until the expiration of their terms. Upon*
24 *such termination, the nominating committee, in*
25 *submitting nominations to fill such vacancies,*

1 *shall ensure the staggered rotation of $\frac{1}{3}$ of the*
2 *members elected under paragraph (2) every 3*
3 *years.*

4 “(D) *CONTRACT STATUS.*—*A change in the*
5 *status of a contract under subsection (f), or a*
6 *change in the contractor, shall not affect the*
7 *terms of the members of the OPTN Board.*

8 “(5) *CHAIRPERSON AND COMMITTEES.*—*The*
9 *OPTN Board shall have a chairperson, an executive*
10 *committee, a nominating committee, a membership*
11 *committee, and such other committees as the OPTN*
12 *Board determines to be appropriate.*

13 “(c) *GENERAL FUNCTIONS OF THE OPTN BOARD.*—

14 “(1) *ESTABLISHMENT OF NETWORK POLICIES*
15 *AND CRITERIA.*—*The OPTN Board shall—*

16 “(A) *after consultation with Network par-*
17 *ticipants and the Network Administrator, estab-*
18 *lish and carry out the policies and functions de-*
19 *scribed in this section for the Network;*

20 “(B) *establish membership criteria for par-*
21 *ticipating in the Network;*

22 “(C) *establish medical criteria for allocating*
23 *organs and for listing and de-listing patients on*
24 *the national lists maintained under paragraph*
25 *(2); and*

1 “(D) *establish performance criteria for*
2 *transplant programs.*

3 “(2) *NATIONAL SYSTEM.—The OPTN Board*
4 *shall maintain a national system to match organs*
5 *and individuals who need organ transplants. The na-*
6 *tional system shall—*

7 “(A) *have 1 or more lists, derived from a*
8 *national list, of individuals who are in need of*
9 *organ transplants; and*

10 “(B) *be operated in accordance with Net-*
11 *work policies and criteria established under*
12 *paragraph (1).*

13 “(3) *NO FIDUCIARY RESPONSIBILITY.—The*
14 *OPTN Board shall have no voting member who has*
15 *any fiduciary responsibility to the entity that holds*
16 *the contract provided for under this section.*

17 “(4) *OPTN BOARD REQUIREMENTS.—The OPTN*
18 *Board shall cooperate with the Network Adminis-*
19 *trator to ensure compliance with the requirements of*
20 *this section including the contract entered into under*
21 *subsection (f).*

22 “(d) *ORGAN TRANSPLANT POLICY.—The OPTN Board*
23 *shall establish organ transplant policies, including organ*
24 *allocation policies for potential organ recipients and poli-*
25 *cies that affect patient outcomes. Such policies shall—*

1 “(1) be based on sound medical principles;

2 “(2) be based on valid scientific data;

3 “(3) be equitable;

4 “(4) seek to achieve the best use of donated or-
5 gans;

6 “(5) be designed to avoid wasting organs, to
7 avoid futile transplants and reduce the risk of re-
8 transplantation, to promote patient access to trans-
9 plantation, and to promote the efficient management
10 of organ placement;

11 “(6) be specific for each organ type or combina-
12 tion of organ types;

13 “(7) be based on standardized medical criteria
14 for listing and de-listing candidates from organ
15 transplant waiting lists;

16 “(8) determine priority rankings (within cat-
17 egories as appropriate) for candidates who are medi-
18 cally suitable for transplantation, such rankings shall
19 be based on standardized medical criteria and ordered
20 according to medical urgency and medical appro-
21 priateness;

22 “(9) seek to reduce disparities in transplantation
23 resulting from socioeconomic status, race, ethnicity,
24 geographic area or region of residence or transplan-
25 tation, or being medically underserved;

1 “(10) develop and apply appropriate perform-
 2 ance indicators, including patient-focused indicators,
 3 to assess transplant program performance and reduce
 4 inter-transplant program variance to improve pro-
 5 gram performance; and

6 “(11) seek distribution of organs as appropriate
 7 based on paragraphs (1) through (10).

8 “(e) ENFORCEMENT OF ORGAN TRANSPLANT POL-
 9 ICY.—

10 “(1) IN GENERAL.—

11 “(A) PROPOSED POLICY.—This paragraph
 12 shall apply to any proposed transplant policy
 13 that is developed by the OPTN Board that the
 14 Board or the Secretary determines should be en-
 15 forced under this section or under section 1138
 16 of the Social Security Act.

17 “(B) SUBMISSION OF POLICY.—

18 “(i) IN GENERAL.—Not later than 60
 19 days prior to the implementation of a pro-
 20 posed policy described in subparagraph (A),
 21 the OPTN Board shall submit such pro-
 22 posed policy to the Secretary.

23 “(ii) REQUIRED SUBMISSION.—

24 “(I) REQUEST BY SECRETARY.—If
 25 determined appropriate by the Sec-

1 *retary, the Secretary may request that*
2 *the OPTN Board submit revisions to*
3 *existing transplant policies, or submit*
4 *new transplant policies, to the Sec-*
5 *retary under this subparagraph. Not*
6 *later than 90 days after any such re-*
7 *quest, the OPTN Board shall submit*
8 *such revisions or new policy to the Sec-*
9 *retary.*

10 *“(II) FAILURE TO COMPLY.—If*
11 *the OPTN Board fails to comply with*
12 *the request of the Secretary under sub-*
13 *clause (I), the Secretary may submit*
14 *comments concerning such request to*
15 *the OPTN Board for review. Not later*
16 *than 60 days after the submission of*
17 *such comments, the OPTN Board shall,*
18 *after considering such comments,*
19 *transmit the policy to the Secretary for*
20 *review under subparagraph (C).*

21 *“(III) APPLICATION OF PROVI-*
22 *SIONS.—The provisions of subpara-*
23 *graphs (C), (D), and (E) shall apply*
24 *to any revisions or new policies sub-*
25 *mitted under this clause to the same*

1 *extent that such subparagraphs apply*
2 *to policies proposed under subpara-*
3 *graph (A).*

4 “(C) *PUBLICATION.*—*Upon receipt of a pro-*
5 *posed policy under subparagraph (B), the Sec-*
6 *retary shall publish the policy in the Federal*
7 *Register for a 60-day public comment period.*

8 “(D) *ACTION BY SECRETARY.*—*Not later*
9 *than 90 days after receipt of a proposed policy*
10 *under subparagraph (B), the Secretary shall con-*
11 *sider public comments received under subpara-*
12 *graph (C) and shall—*

13 “(i) *notify the OPTN Board that the*
14 *policy is consistent with this section and*
15 *therefore enforceable; or*

16 “(ii) *notify the OPTN Board that the*
17 *policy is inconsistent with this section and*
18 *direct the Board to reconsider and revise the*
19 *policy consistent with the recommendations*
20 *of the Secretary.*

21 “(E) *RECONSIDERATION.*—

22 “(i) *IN GENERAL.*—*Not later than 30*
23 *days after receiving a notice from the Sec-*
24 *retary under subparagraph (D)(ii), the*
25 *OPTN Board shall reaffirm the proposed*

1 *policy and submit such policy to the Sec-*
2 *retary or shall revise such policy and sub-*
3 *mit such revised policy to the Secretary.*

4 “(i) *ACTION BY SECRETARY.—Not*
5 *later than 30 days after receiving a revised*
6 *or reaffirmed policy under clause (i), the*
7 *Secretary shall—*

8 “(I) *notify the OPTN Board that*
9 *the revised or reaffirmed policy is con-*
10 *sistent with this section and therefore*
11 *enforceable; or*

12 “(II) *notify the OPTN Board that*
13 *the revised or reaffirmed policy is in-*
14 *consistent with this section and submit*
15 *the revised or reaffirmed policy, with*
16 *the comments and proposed revisions of*
17 *the Secretary, to the Scientific Advi-*
18 *sory Committee on Organ Transplan-*
19 *tation (referred to in this subsection as*
20 *the ‘Committee’) established under*
21 *paragraph (2).*

22 “(iii) *ACTION BY COMMITTEE.—Not*
23 *later than 30 days after the submission of*
24 *a revised or reaffirmed policy to the Com-*
25 *mittee under clause (ii), the Committee*

1 *may, by a majority vote, disapprove the*
2 *comments or revisions of the Secretary. If*
3 *the policy is not disapproved by a majority*
4 *vote, the OPTN Board shall revise the pol-*
5 *icy accordingly and such policy shall be en-*
6 *forceable. If the Committee disapproves such*
7 *comments or revisions, the revised or re-*
8 *affirmed policy shall not take effect until a*
9 *majority of the Committee approves the pol-*
10 *icy or the revisions to such policy. Upon the*
11 *approval of a majority of the Committee of*
12 *the policy or revisions to such policy, the*
13 *OPTN Board shall revise the policy accord-*
14 *ingly and such policy shall become enforce-*
15 *able.*

16 “(2) *SCIENTIFIC ADVISORY COMMITTEE ON*
17 *ORGAN TRANSPLANTATION.—*

18 “(A) *ESTABLISHMENT.—The Secretary shall*
19 *establish an advisory committee to be known as*
20 *the Scientific Advisory Committee on Organ*
21 *Transplantation. Consistent with the require-*
22 *ments of sections 5 and 10 of the Federal Advi-*
23 *sory Committee Act—*

24 “(i) *the deliberations of the Committee*
25 *shall not be inappropriately influenced by*

1 *the Secretary or by any special interest and*
2 *shall only be the result of the independent*
3 *judgment of the Committee; and*

4 “(i) *the meetings of the Committee*
5 *shall be open to the public, advance notice*
6 *of meetings shall be published in the Federal*
7 *Register, and records or minutes of meetings*
8 *shall be made available to the public.*

9 “(B) *DUTIES.—The Committee shall make*
10 *recommendations with respect to policy matters*
11 *related to reviews conducted under paragraph*
12 *(1)(E)(i)(II).*

13 “(C) *MEMBERSHIP.—The Committee shall*
14 *be composed of 21 members, of which—*

15 “(i) *seven members shall be appointed*
16 *by the Secretary from nominations sub-*
17 *mitted by the OPTN Board under subpara-*
18 *graph (D);*

19 “(ii) *seven members shall be appointed*
20 *by the Secretary from nominations sub-*
21 *mitted by the Institute of Medicine under*
22 *subparagraph (D); and*

23 “(iii) *seven members shall be ap-*
24 *pointed by the Secretary.*

1 “(D) *NOMINATIONS.*—*The OPTN Board*
2 *and the Institute of Medicine shall each nomi-*
3 *nate, in an independent manner, 12 qualified*
4 *individuals to serve on the Committee.*

5 “(E) *QUALIFICATIONS.*—*In appointing in-*
6 *dividuals to serve on the Committee under sub-*
7 *paragraph (C), the Secretary shall ensure that—*

8 “(i) *twelve members are transplant*
9 *physicians or transplant surgeons of*
10 *whom—*

11 “(I) *four shall be selected from the*
12 *nominations submitted by the OPTN*
13 *Board; and*

14 “(II) *four shall be selected from*
15 *the nominations submitted by the In-*
16 *stitute of Medicine; and*

17 “(ii) *the remaining members are indi-*
18 *viduals who are—*

19 “(I) *distinguished in the fields of*
20 *ethics, basic, clinical or health services*
21 *research, biostatistics, or health care*
22 *policy, economics or financing; or*

23 “(II) *transplant candidates,*
24 *transplant recipients, organ donors or*
25 *family members of such individuals.*

1 “(F) *EXPERTS.*—*The Committee shall seek*
2 *advice from appropriate experts, as needed, to*
3 *evaluate the proposed policy and revisions under*
4 *review.*

5 “(G) *CHAIRPERSON.*—*The members of the*
6 *Committee shall elect a member to serve as the*
7 *chairperson of the Committee.*

8 “(H) *TERMS.*—*Members of the Committee*
9 *shall serve for a term of 5 years. Vacancies shall*
10 *be filled in the same manner as the original ap-*
11 *pointment was made.*

12 “(3) *STUDY BY GENERAL ACCOUNTING OFFICE.*—

13 “(A) *IN GENERAL.*—*The Comptroller Gen-*
14 *eral shall conduct a study of the review process*
15 *for enforceable transplant policies under this*
16 *subsection. Such study shall examine the role of*
17 *the Advisory Committee established under para-*
18 *graph (2) in resolving transplant policy matters*
19 *under this subsection.*

20 “(B) *COMPLETION AND REPORT.*—*Not later*
21 *than September 30, 2004, the Comptroller Gen-*
22 *eral shall complete the study under subpara-*
23 *graph (A) and shall prepare and submit to the*
24 *appropriate committees of Congress a report that*
25 *contains—*

1 “(i) the findings of the Comptroller
2 General with respect to the study; and

3 “(ii) the recommendations of the
4 Comptroller General concerning—

5 “(I) the continued use of the Advi-
6 sory Committee to resolve transplant
7 policy matters under this subsection;

8 “(II) improvements in the com-
9 position and method of selection of the
10 members of the Advisory Committee;
11 and

12 “(III) any other improvements in
13 the review process.

14 “(f) NETWORK ADMINISTRATION AND OPERATION.—
15 The Secretary shall contract with a nonprofit private entity
16 (referred to in this section as the ‘Network Administrator’)
17 for the administration and operation of the Network. The
18 Network Administrator shall administer and operate the
19 OPTN Board in accordance with subsection (b). The Net-
20 work Administrator shall, pursuant to the policies and cri-
21 teria established by the OPTN Board—

22 “(1) maintain and operate a national system as
23 established by the OPTN Board to match organs and
24 individuals who need organ transplants;

1 “(2) operate in accordance with medical criteria
2 established by the OPTN Board, and administer the
3 national system established under subsection (c)(2);

4 “(3) maintain 1 or more lists, derived from a
5 national list, of individuals who need organ trans-
6 plants as provided for under subsection (c)(2)(A);

7 “(4) maintain a 24-hour communication service
8 to facilitate matching organs with individuals in-
9 cluded on the list or lists;

10 “(5) assist organ procurement organizations in
11 obtaining and distributing organs in accordance with
12 the policies established by the OPTN Board;

13 “(6) adopt and use standards of quality for the
14 acquisition and transportation of donated organs, in-
15 cluding standards regarding the transmission of in-
16 fectious diseases;

17 “(7) prepare and distribute, on a regionalized
18 basis (and, to the extent practicable, among regions or
19 on a national basis), samples of blood sera from indi-
20 viduals who are included on the list in order to facili-
21 tate matching the compatibility of such individuals
22 with organ donors;

23 “(8) coordinate, as appropriate, the transpor-
24 tation of organs from organ procurement organiza-
25 tions to transplant centers;

1 “(9) provide information to physicians, health
2 care professionals, and the general public regarding
3 organ donation;

4 “(10) carry out studies and demonstration
5 projects for the purpose of improving procedures for
6 organ procurement and allocation; and

7 “(11) work actively with organ procurement or-
8 ganizations, transplant centers, health care providers,
9 and the public to increase the supply of donated or-
10 gans.

11 “(g) *DATA COLLECTION, ANALYSIS AND DISTRIBUTION.*—
12

13 “(1) *IN GENERAL.*—*The Network Administrator*
14 *shall analyze, maintain, verify, make available and*
15 *publish timely data to the extent necessary to—*

16 “(A) *enable the OPTN Board to fulfill its*
17 *responsibilities under this section;*

18 “(B) *assess the compliance of members of*
19 *the Network with performance and other criteria*
20 *developed pursuant to subsection (c)(1);*

21 “(C) *evaluate the quality of care provided to*
22 *transplant candidates and patients generally*
23 *and in an individual program;*

24 “(D) *provide data needed by the Scientific*
25 *Registry maintained pursuant to section 373;*

1 “(E) provide transplant candidates and pa-
2 tients, physicians and others with information
3 needed to evaluate or select a transplant pro-
4 gram;

5 “(F) provide a member of the Network with
6 data about the member, including results of
7 analysis or other processing of data originally
8 supplied by the member;

9 “(G) enable the OPTN Board, the Network
10 Administrator and the Secretary to fulfill their
11 responsibilities under this section; and

12 “(H) comply with the requirements under
13 subsection (l).

14 “(2) TYPES OF DATA.—Data provided under
15 paragraph (1) shall include—

16 “(A) data on transplant candidates, trans-
17 plant recipients, organ donors, donated organs,
18 and transplant programs; and

19 “(B) as appropriate, data, graft- and pa-
20 tient-survival rates (actual and adjusted to re-
21 flect program-specific population disease sever-
22 ity), program specific data, and aggregate data.

23 “(h) CONTRACT.—The contract under subsection (f)
24 shall—

1 “(1) be awarded through a process of competitive
2 bidding as determined by the Secretary; and

3 “(2) be awarded for a period of no longer than
4 5 years.

5 “(i) *NETWORK MEMBERSHIP AND PATIENT REGISTRA-*
6 *TION FEE.*—

7 “(1) *IN GENERAL.*—*The Network Administrator*
8 *may assess a fee, to be collected by the Network Ad-*
9 *ministrator, for membership in the Network (to be*
10 *known as the ‘Network membership fee’), and for the*
11 *listing of each potential transplant recipient on the*
12 *national organ matching system maintained by the*
13 *Network Administrator (to be known as the ‘patient*
14 *registration fee’), in an amount determined under*
15 *paragraph (2).*

16 “(2) *AMOUNT.*—*The amounts of the fees to be as-*
17 *essed under paragraph (1) shall be calculated so as*
18 *to be—*

19 “(A) *reasonable and customary; and*

20 “(B) *sufficient to cover the Network’s rea-*
21 *sonable costs of operation in accordance with*
22 *this section.*

23 “(3) *ANNUAL RECALCULATION.*—

1 “(A) *IN GENERAL.*—*The fees calculated*
2 *under paragraph (2) shall be annually recal-*
3 *culated, based on—*

4 “(i) *changes in the level or cost of con-*
5 *tract tasks and other activities related to*
6 *organ procurement and transplantation;*
7 *and*

8 “(ii) *changes in expected revenues from*
9 *contract funds, Network membership fees*
10 *and patient registration fees available to the*
11 *Network Administrator.*

12 “(B) *PROCEDURE.*—

13 “(i) *PROPOSAL.*—*The Network Admin-*
14 *istrator shall submit to the Secretary a*
15 *written proposal for, and justification of, a*
16 *recalculated fee under subparagraph (A).*

17 “(ii) *DETERMINATION.*—*The proposal*
18 *of the Network Administrator for a recal-*
19 *culated fee under clause (i) shall take effect*
20 *unless the Secretary, within 60 days of re-*
21 *ceiving the proposal, provides the Network*
22 *Administrator with a written determina-*
23 *tion, with justification, that the proposed*
24 *fee level does not meet the requirement of*
25 *subparagraph (A).*

1 “(4) *USE OF FEES.*—

2 “(A) *IN GENERAL.*—*All fees collected by the*
3 *Network Administrator under this subsection*
4 *shall be available to the Network, without fiscal*
5 *year limitation, for use in carrying out the func-*
6 *tions described in subsection (f).*

7 “(B) *RESTRICTION.*—*Fees collected under*
8 *this subsection may not be used for any activity*
9 *for which contract funds may not be used under*
10 *this section.*

11 “(5) *RULE OF CONSTRUCTION.*—*Nothing in this*
12 *subsection shall be construed as prohibiting the Net-*
13 *work Administrator from collecting or accepting other*
14 *fees, donations or gifts or for using such other fees, do-*
15 *nations or gifts to carry out activities other than*
16 *those authorized under the contract under this section.*

17 “(j) *OVERSIGHT OF NETWORK PARTICIPANTS.*—

18 “(1) *MONITORING.*—

19 “(A) *IN GENERAL.*—*The OPTN Board and*
20 *the Network Administrator shall, on an ongoing*
21 *and periodic basis, or as requested by the Sec-*
22 *retary, monitor the operations of Network par-*
23 *ticipants to determine whether the participants*
24 *are maintaining compliance with the criteria*
25 *and policies established by the OPTN Board.*

1 “(B) *PROCEDURES.*—

2 “(i) *NOTICE.*—*In monitoring a Net-*
3 *work participant under subparagraph (A),*
4 *the OPTN Board or the Administrator—*

5 “(I) *shall inform the participant*
6 *and the Secretary upon initiating a*
7 *compliance review of a Network partic-*
8 *ipant; and*

9 “(II) *shall inform the participant*
10 *and the Secretary of any findings indi-*
11 *cating noncompliance by the partici-*
12 *part with such criteria and policies.*

13 “(ii) *APPEALS.*—*The Network Admin-*
14 *istrator shall establish procedures for ap-*
15 *pealing noncompliance determinations.*
16 *Such procedures shall ensure due process*
17 *and shall allow for corrective action.*

18 “(2) *PEER REVIEW PROCEEDINGS.*—

19 “(A) *IN GENERAL.*—*The OPTN Board shall*
20 *establish a peer review system and conditions for*
21 *the application of peer review requirements to*
22 *ensure that members of the Network comply with*
23 *policies and criteria established by the OPTN*
24 *Board under this section. Such peer review sys-*
25 *tem may include prospective reviews and shall be*

1 *administered by the Network Administrator and*
2 *overseen by the OPTN Board.*

3 “(B) *POLICIES, REVIEW AND EVALUA-*
4 *TION.—As part of the peer review system estab-*
5 *lished under subparagraph (A), the OPTN Board*
6 *shall establish such policies, and the Network Ad-*
7 *ministrator shall conduct such ongoing and peri-*
8 *odic reviews and evaluations of members of the*
9 *Network, as necessary to ensure compliance with*
10 *the policies and criteria established by the OPTN*
11 *Board under this section.*

12 “(C) *EMERGING ISSUES.—As part of such*
13 *peer review system established under subpara-*
14 *graph (A), the OPTN Board shall establish poli-*
15 *cies to work with and direct the Network Admin-*
16 *istrator to respond to emerging issues and prob-*
17 *lems.*

18 “(k) *ENFORCEMENT.—*

19 “(1) *RECOMMENDATIONS.—The OPTN Board or*
20 *the Network Administrator shall provide advice, and*
21 *make recommendations for appropriate action, to the*
22 *Secretary concerning the results of any reviews or*
23 *evaluations that, in the opinion of the OPTN Board*
24 *or the Network Administrator, indicate—*

1 “(A) noncompliance by Network partici-
2 pants with—

3 “(i) the policies or criteria established
4 by the OPTN Board; or

5 “(ii) the operating procedures of the
6 Network Administrator; or

7 “(B) a risk to the health of organ trans-
8 plant patients or to public safety.

9 “(2) ENFORCEMENT BY NETWORK.—

10 “(A) IN GENERAL.—If the OPTN Board de-
11 termines that one of the members of the network
12 has violated a requirement established by this
13 section or by the Network, the OPTN Board may
14 impose on the member 1 or more of the sanctions
15 described in subparagraph (B), or may rec-
16 ommend that the Secretary take enforcement ac-
17 tion under paragraph (3).

18 “(B) TYPES OF SANCTIONS.—The sanctions
19 described in this subparagraph may include—

20 “(i) the loss of any or all privileges of
21 membership in good standing in the Net-
22 work;

23 “(ii) the imposition upon the member
24 of additional or more frequent reviews or
25 evaluations under subsection (j)(1)(A), and

1 *assessments of the reasonable costs of such*
2 *additional or more frequent reviews or eval-*
3 *uations; and*

4 “(iii) *such other sanctions as the Sec-*
5 *retary may permit the OPTN Board to im-*
6 *pose.*

7 “(3) *ENFORCEMENT BY THE SECRETARY.—*

8 “(A) *IN GENERAL.—If the Secretary, after*
9 *consultation with the OPTN Board or Network*
10 *Administrator, determines that a member of the*
11 *Network has violated a requirement established*
12 *by this section or a requirement of a policy that*
13 *is enforceable under subsection (f), the Secretary*
14 *may impose on the member 1 or more of the*
15 *sanctions described in subparagraph (B).*

16 “(B) *TYPES OF SANCTIONS.—The sanctions*
17 *described in this subparagraph shall include—*

18 “(i) *requiring the member to follow a*
19 *directed plan of correction;*

20 “(ii) *imposing upon the member a*
21 *monetary assessment (to be paid to the Gen-*
22 *eral Fund of the Treasury) in an amount*
23 *not to exceed \$10,000 for each violation or*
24 *for each day of violation;*

1 “(iii) requiring the member to pay to
2 the Network Administrator the costs of on-
3 site monitoring of the member;

4 “(iv) the loss of any or all privileges of
5 membership in the Network; and

6 “(v) in cases where the violation cre-
7 ates a risk to patient health or to public
8 health, such other action as the Secretary
9 determines to be necessary.

10 “(C) PROCEDURES.—The Secretary shall
11 develop and implement procedures for the impo-
12 sition of sanctions under clauses (i) through (v)
13 of subparagraph (B). Such procedures shall
14 include—

15 “(i) the provision of reasonable notice
16 to the Network member and the OPTN
17 Board that the Secretary is considering im-
18 posing a sanction;

19 “(ii) affording the member a reason-
20 able opportunity to be heard in response to
21 the notice;

22 “(iii) the provision of notice to the
23 member that the Secretary has decided to
24 impose a sanction; and

1 “(iv) the opportunity for the Network
2 member to appeal such sanction.

3 “(l) ANNUAL REPORT.—

4 “(1) IN GENERAL.—Not later than September 30
5 of each year, the Network Administrator shall prepare
6 and submit to the Secretary an annual report on the
7 performance and policies of the Network. The report
8 shall include additional items as specified in the con-
9 tract under this section or requested in a timely man-
10 ner by the Secretary.

11 “(2) REQUIREMENT OF OPTN BOARD AP-
12 PROVAL.—The OPTN Board shall review and approve
13 the report required under paragraph (1) prior to the
14 submission of such report to the Secretary.

15 “(3) SUBMISSION TO CONGRESS.—

16 “(A) IN GENERAL.—Not later than Decem-
17 ber 31 of each year, the Secretary shall transmit
18 the report submitted under paragraph (1) and
19 the comments of the Secretary concerning such
20 report, to the appropriate committees of Con-
21 gress.

22 “(B) CLARIFYING INFORMATION.—The Sec-
23 retary may, upon the receipt of the report under
24 paragraph (1), but prior to transmission of the
25 report to Congress under subparagraph (A), re-

1 *quest that the Network Administrator submit*
2 *clarifying information or an addenda as needed*
3 *to fulfill the requirements of this subsection.*

4 “(m) *AUTHORIZATION OF APPROPRIATIONS.—There is*
5 *authorized to be appropriated to carry out this section, such*
6 *sums as may be necessary for each of fiscal years 2001*
7 *through 2005.”.*

8 **SEC. 3. SCIENTIFIC REGISTRY.**

9 *Section 373 of the Public Health Service Act (42*
10 *U.S.C. 274a) is amended to read as follows:*

11 **“SEC. 373. SCIENTIFIC REGISTRY.**

12 *“The Secretary shall by contract, develop and main-*
13 *tain a scientific registry of the recipients of organ trans-*
14 *plants. The registry shall include information, with respect*
15 *to organ transplant patients and transplant procedures, as*
16 *the Secretary determines to be necessary to an ongoing eval-*
17 *uation of the scientific and clinical status of organ trans-*
18 *plantation.”.*

19 **SEC. 4. ORGAN DONATION.**

20 *Part H of title III of the Public Health Service Act*
21 *(42 U.S.C. 273 et seq.) is amended—*

22 (1) *by redesignating section 378 (42 U.S.C.*
23 *274g) as section 379; and*

24 (2) *by inserting after section 377 (42 U.S.C.*
25 *274f) the following:*

1 **“SEC. 378. ORGAN DONATION AND RESEARCH.**

2 “(a) *INTER-AGENCY TASK FORCE ON ORGAN DONA-*
3 *TION AND RESEARCH.—*

4 “(1) *IN GENERAL.—The Secretary shall establish*
5 *an inter-agency task force on organ donation and re-*
6 *search (referred to in this section as the ‘task force’)*
7 *to improve the coordination and evaluation of—*

8 “(A) *federally supported or conducted organ*
9 *donation efforts and policies; and*

10 “(B) *federally supported or conducted basic,*
11 *clinical and health services research (including*
12 *research on preservation techniques and organ*
13 *rejection and compatibility).*

14 “(2) *COMPOSITION.—The task force shall be com-*
15 *posed of—*

16 “(A) *the Surgeon General, who shall serve*
17 *as the chairperson;*

18 “(B) *representatives to be appointed by the*
19 *Secretary from relevant agencies within the De-*
20 *partment of Health and Human Services (in-*
21 *cluding the Health Resources and Services Ad-*
22 *ministration, Health Care Financing Adminis-*
23 *tration, National Institutes of Health, and Agen-*
24 *cy for Healthcare Research and Quality);*

25 “(C) *a representative from the Department*
26 *of Transportation;*

1 “(D) a representative from the Department
2 of Defense;

3 “(E) a representative from the Department
4 of Veterans Affairs;

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

7 “(G) representatives of other Federal agen-
8 cies or departments as determined to be appro-
9 priate by the Secretary.

10 “(3) ANNUAL REPORT.—In addition to activities
11 carried out under paragraph (1), the task force shall
12 support the development of the annual report under
13 subsection (d)(2).

14 “(4) TERMINATION.—The task force may be ter-
15 minated at the discretion of the Secretary following
16 the completion of at least 2 annual reports under sub-
17 section (d). Upon such termination, the Secretary
18 shall provide for the on-going coordination of feder-
19 ally supported or conducted organ donation and re-
20 search activities.

21 “(b) EDUCATION.—

22 “(1) PUBLIC EDUCATION AND AWARENESS.—The
23 Secretary shall, directly or through grants or con-
24 tracts, carry out a comprehensive and effective na-

1 *tional public education program to increase organ do-*
2 *nation, including living donation.*

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

5 *“(A) IN GENERAL.—The Secretary shall*
6 *support the development and dissemination of*
7 *model curricula to train health care professionals*
8 *and other appropriate professionals (including*
9 *religious leaders in the community and law en-*
10 *forcement officials) in issues surrounding organ*
11 *donation, including methods to approach pa-*
12 *tients and their families, cultural sensitivities,*
13 *and other relevant issues.*

14 *“(B) HEALTH CARE PROFESSIONALS.—For*
15 *purposes of subparagraph (A), the term ‘health*
16 *care professionals’ includes—*

17 *“(i) medical students, residents and*
18 *fellows, attending physicians (through con-*
19 *tinuing medical education courses and other*
20 *methods), nurses, social workers, and other*
21 *allied health professionals; and*

22 *“(ii) hospital- or other health care-fa-*
23 *cility based chaplains; and*

24 *“(iii) emergency medical personnel.*

1 “(c) GRANTS.—The Secretary shall award peer-re-
2 viewed grants to public and non-profit private entities, in-
3 cluding States, to carry out studies and demonstration
4 projects to increase organ donation rates, including living
5 donation. The Secretary shall ensure that activities carried
6 out by grantees under this subsection are evaluated for effec-
7 tiveness and that such findings are disseminated.

8 “(d) REPORTS.—

9 “(1) IOM REPORT ON BEST PRACTICES.—

10 “(A) IN GENERAL.—The Secretary shall
11 enter into a contract with the Institute of Medi-
12 cine to conduct an evaluation of the organ dona-
13 tion practices of organ procurement organiza-
14 tions, States, other countries, and other appro-
15 priate organizations that have achieved a higher
16 than average organ donation rate.

17 “(B) BARRIERS.—In conducting the evalua-
18 tion under subparagraph (A), the Institute of
19 Medicine shall examine existing barriers to
20 organ donation.

21 “(C) REPORT.—Not later than 18 months
22 after the date of enactment of this section, the In-
23 stitute of Medicine shall submit to the Secretary
24 a report concerning the evaluation conducted
25 under this paragraph. Such report shall include

1 *recommendations for administrative actions and,*
2 *if necessary, legislation in order to replicate the*
3 *best practices identified in the evaluation and to*
4 *otherwise increase organ donation and procure-*
5 *ment rates.*

6 “(2) *ANNUAL REPORT ON DONATION.*—

7 “(A) *IN GENERAL.*—*Not later than 1 year*
8 *after the date on which the report is submitted*
9 *under paragraph (1)(C), and annually there-*
10 *after, the Secretary shall prepare and submit to*
11 *Congress a report concerning federally supported*
12 *or conducted organ donation and procurement*
13 *activities, including donation and procurement*
14 *activities evaluated or conducted under sub-*
15 *section (a) to increase organ donation.*

16 “(B) *REQUIREMENTS.*—*To the extent prac-*
17 *ticable, each annual report under subparagraph*
18 *(A) shall—*

19 “(i) *evaluate the effectiveness of activi-*
20 *ties, identify best practices, and make rec-*
21 *ommendations regarding broader adoption*
22 *of best practices with respect to organ dona-*
23 *tion and procurement;*

1 “(ii) assess organ donation and pro-
2 curement activities that are recently com-
3 pleted, current or planned.

4 “(e) *AUTHORIZATION OF APPROPRIATIONS.*—There is
5 authorized to be appropriated to carry out this section,
6 \$15,000,000 for fiscal year 2001, and such sums as may
7 be necessary for each of fiscal years 2002 through 2005.”.

8 **SEC. 5. ORGAN PROCUREMENT ORGANIZATION CERTIFI-**
9 **CATION.**

10 (a) *FINDINGS.*—Congress makes the following findings:

11 (1) *Organ procurement organizations play an*
12 *important role in the effort to increase organ dona-*
13 *tion in the United States.*

14 (2) *The current process for the certification and*
15 *recertification of organ procurement organizations*
16 *conducted by the Department of Health and Human*
17 *Services has created a level of uncertainty that is*
18 *interfering with the effectiveness of organ procurement*
19 *organizations in raising the level of organ donation.*

20 (3) *The General Accounting Office, the Institute*
21 *of Medicine, and the Harvard School of Public Health*
22 *have identified substantial limitations in the organ*
23 *procurement organization certification and recertifi-*
24 *cation process and have recommended changes in that*
25 *process.*

1 (4) *The limitations in the recertification process*
2 *include:*

3 (A) *An exclusive reliance on population-*
4 *based measures of performance that do not ac-*
5 *count for the potential in the population for*
6 *organ donation and do not permit consideration*
7 *of other outcome and process standards that*
8 *would more accurately reflect the relative capa-*
9 *bility and performance of each organ procure-*
10 *ment organization.*

11 (B) *A lack of due process to appeal to the*
12 *Secretary of Health and Human Services for re-*
13 *certification on either substantive or procedural*
14 *grounds.*

15 (5) *The Secretary of Health and Human Serv-*
16 *ices has the authority under section 1138(b)(1)(A)(i)*
17 *of the Social Security Act (42 U.S.C. 1320b-*
18 *8(b)(1)(A)(i)) to extend the period for recertification*
19 *of an organ procurement organization from 2 to 4*
20 *years on the basis of its past practices in order to*
21 *avoid the inappropriate disruption of the nation's*
22 *organ system.*

23 (6) *The Secretary of Health and Human Serv-*
24 *ices can use the extended period described in para-*

1 *graph (5) for recertification of all organ procurement*
 2 *organizations to—*

3 *(A) develop improved performance measures*
 4 *that would reflect organ donor potential and in-*
 5 *terim outcomes, and to test these measures to en-*
 6 *sure that they accurately measure performance*
 7 *differences among the organ procurement organi-*
 8 *zations; and*

9 *(B) improve the overall certification process*
 10 *by incorporating process as well as outcome per-*
 11 *formance measures, and developing equitable*
 12 *processes for appeals.*

13 *(b) CERTIFICATION AND RECERTIFICATION OF ORGAN*
 14 *PROCUREMENT ORGANIZATIONS.—Section 371(b)(1) of the*
 15 *Public Health Service Act (42 U.S.C. 273(b)(1)) is*
 16 *amended—*

17 *(1) by redesignating subparagraphs (D) through*
 18 *(G) as subparagraphs (E) through (H), respectively;*

19 *(2) by realigning the margin of subparagraph*
 20 *(F) (as so redesignated) so as to align with subpara-*
 21 *graph (E) (as so redesignated); and*

22 *(3) by inserting after subparagraph (C) the fol-*
 23 *lowing:*

24 *“(D) notwithstanding any other provision of*
 25 *law, has met the other requirements of this section*

1 *and has been certified or recertified by the Secretary*
2 *within the previous 4-year period as meeting the per-*
3 *formance standards to be a qualified organ procure-*
4 *ment organization through a process that either—*

5 *“(i) granted certification or recertification*
6 *within such 4-year period with such certification*
7 *or recertification in effect as of January 1, 2000,*
8 *and remaining in effect through the earlier of—*

9 *“(I) January 1, 2002; or*

10 *“(II) the completion of recertification*
11 *under the requirements of clause (ii); or*

12 *“(ii) is defined through regulations that are*
13 *promulgated by the Secretary by not later than*
14 *January 1, 2002, that—*

15 *“(I) require recertifications of qualified*
16 *organ procurement organizations not more*
17 *frequently than once every 4 years;*

18 *“(II) rely on outcome and process per-*
19 *formance measures that are based on empir-*
20 *ical evidence, obtained through reasonable*
21 *efforts, of organ donor potential and other*
22 *related factors in each service area of quali-*
23 *fied organ procurement organizations;*

24 *“(III) use multiple outcome measures*
25 *as part of the certification process; and*

1 “(IV) provide for a qualified organ
2 procurement organization to appeal a decer-
3 tification to the Secretary on substantive
4 and procedural grounds;”.

5 **SEC. 6. TECHNICAL AMENDMENT.**

6 Subparagraph (E) of section 371(b)(3) of the Public
7 Health Service Act (42 U.S.C. 273(b)(3)(E)) is amended
8 to read as follows:

9 “(E) assist the Organ Procurement and Trans-
10 plantation Network in the allocation of donated or-
11 gans in accordance with the policies and criteria es-
12 tablished pursuant to section 372,”.

13 **SEC. 7. STUDY REGARDING IMMUNOSUPPRESSIVE DRUGS.**

14 (a) *IN GENERAL.*—The Secretary of Health and
15 Human Services (referred to in this section as the “Sec-
16 retary”) shall provide for a study to determine the costs
17 of immunosuppressive drugs that are provided to children
18 pursuant to organ transplants and to determine the extent
19 to which health plans, health insurance, and Government
20 programs cover such costs. The Secretary may carry out
21 the study directly or through a grant to the Institute of
22 Medicine (or other public or nonprofit private entity).

23 (b) *RECOMMENDATIONS REGARDING CERTAIN*
24 *ISSUES.*—The Secretary shall ensure that, in addition to
25 making determinations under subsection (a), the study

1 *under such subsection makes recommendations regarding*
2 *the following issues:*

3 (1) *The costs of immunosuppressive drugs that*
4 *are provided to children pursuant to organ trans-*
5 *plants and to determine the extent to which health*
6 *plans, health insurance, and Government programs*
7 *cover such costs.*

8 (2) *Other issues that are particular to the special*
9 *health and transplantation needs of children.*

10 (c) *REPORT.—The Secretary shall ensure that, not*
11 *later than 6 months after the date of enactment of this Act,*
12 *the study under subsection (a) is completed and a report*
13 *describing the findings of the study is submitted to Con-*
14 *gress.*