

106TH CONGRESS
2^D SESSION

H. R. 2418

AN ACT

To amend the Public Health Service Act to revise and extend programs relating to organ procurement and transplantation.

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 of 2000”.

4 **SEC. 2. FINDINGS.**

5 (a) IN GENERAL.—The Congress finds as follows:

6 (1) It is in the public interest to maintain and
7 improve a system for promoting and supporting a
8 central network in the private sector to assist organ
9 procurement organizations and transplant centers in
10 the distribution of organs among transplant patients
11 and the provision of organ transplantation services,
12 and to assure quality and facilitate collaboration
13 among network members and individual medical
14 practitioners participating in network activities.

15 (2) The Organ Procurement and Transplan-
16 tation Network (“Network”), which was established
17 in the private sector pursuant to a contract awarded
18 by the Federal Government, should continue to be
19 operated by a nonprofit private entity pursuant to a
20 contract with the Federal Government.

21 (3) The Federal Government should continue to
22 provide Federal oversight of and financial assistance
23 for the services provided by the Network.

24 (4) The responsibility for developing, estab-
25 lishing, and maintaining medical criteria and stand-
26 ards for organ procurement and transplantation be-

1 longs in the private sector and is a function of the
2 Network.

3 (5) The Federal Government should assist the
4 efforts of the Network to serve patient and donor
5 families in procuring and distributing organs.

6 (6) The Federal Government should carry out
7 programs to educate the public with respect to organ
8 donation, including the need to provide for an ade-
9 quate rate of such donations.

10 (b) SENSE OF THE CONGRESS REGARDING FAMILY
11 DISCUSSIONS OF ORGAN DONATIONS.—The Congress rec-
12 ognizes the importance of families pledging to each other
13 to share their lives as organ and tissue donors and ac-
14 knowledges the importance of discussing organ and tissue
15 donation as a family.

16 (c) SENSE OF THE CONGRESS REGARDING LIVING
17 DONATIONS OF ORGANS.—The Congress—

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

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

1 **SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION**
2 **NETWORK.**

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

5 “ORGAN PROCUREMENT AND TRANSPLANTATION
6 NETWORK

7 “SEC. 372. (a) IN GENERAL.—The Secretary shall
8 by contract provide for the continuing operation of an
9 Organ Procurement and Transplantation Network (in this
10 section referred to as the ‘Network’), which contract shall
11 be awarded to a nonprofit private entity that has expertise
12 and experience in organ procurement and transplantation.
13 The Network shall meet the following requirements:

14 “(1) The Network shall be an independent,
15 nonprofit private entity that is a separate legal enti-
16 ty from the entity to which such contract is award-
17 ed.

18 “(2) The Network shall in accordance with cri-
19 teria under subsection (b)(3) include as members
20 qualified organ procurement organizations (as de-
21 scribed in section 371(b)), transplant centers, and
22 other entities that have a demonstrated interest in
23 the fields of organ donation or transplantation.
24 (such members are in this section referred to as
25 ‘Network participants’).

1 “(3) The Network shall have a board of direc-
2 tors (in this section referred to as the ‘Board’). The
3 Board shall, after consultation with Network partici-
4 pants, establish the policies for carrying out the
5 functions described in this section for the Network.

6 “(4) The Board shall be in accordance with the
7 following:

8 “(A) The Board shall include representa-
9 tives of qualified organ procurement organiza-
10 tions, transplant centers, voluntary health asso-
11 ciations, and the general public, including a
12 reasonable proportion of the members of the
13 Board who are patients awaiting a transplant
14 or transplant recipients or individuals who have
15 donated an organ or family members of pa-
16 tients, recipients or donors.

17 “(B) The Board shall establish member-
18 ship categories and qualifications with respect
19 to serving on the Board, and shall have exclu-
20 sive authority to admit individuals to member-
21 ship on the Board. Transplant surgeons and
22 transplant physicians shall comprise not less
23 than 50 percent of the membership of the
24 Board. The Board shall be limited to a total of
25 42 members.

1 “(C) The Board shall have an executive
2 committee, and such other committees as the
3 Board determines to be appropriate.

4 “(D) The chair of each such committee
5 shall be selected so as to ensure the continuity
6 of leadership for the Board.

7 “(b) GENERAL FUNCTIONS.—The following applies
8 to the Network:

9 “(1) The Network shall establish and operate a
10 national system to match organs and individuals
11 who need organ transplants, especially individuals
12 whose immune system makes it difficult for them to
13 receive organs.

14 “(2) The national system shall maintain one or
15 more lists of individuals who need organ transplants,
16 shall be operated in accordance with established
17 medical criteria, shall be operated through the use of
18 computers, and may function on a regionalized
19 basis.

20 “(3) The Network shall establish criteria for
21 being a Network participant, shall establish medical
22 criteria for listing patients and for allocating organs,
23 and shall provide to members of the public an oppor-
24 tunity to comment with respect to such criteria.

1 “(4) The Network shall maintain a twenty-four-
2 hour telephone and computer service to facilitate
3 matching organs with individuals included in the
4 list.

5 “(5) The Network shall assist organ procure-
6 ment organizations in the distribution of organs.
7 The distribution of organs shall be based on medical
8 criteria established by the Network, and also shall be
9 based on equity and ethics without regard to eco-
10 nomic status of those awaiting organ transplants
11 and without political control or influence.

12 “(6) The Network shall adopt and use stand-
13 ards of quality for the acquisition and transportation
14 of donated organs, including standards regarding
15 the transmission of infectious diseases.

16 “(7) The Network shall prepare and distribute,
17 on a regionalized basis (and, to the extent prac-
18 ticable, among regions or on a national basis), sam-
19 ples of blood sera from individuals who are included
20 on the list and whose immune system makes it dif-
21 ficult for them to receive organs, in order to facili-
22 tate matching the compatibility of such individuals
23 with organ donors.

1 “(8) The Network shall coordinate, as appro-
2 priate, the transportation of organs from organ pro-
3 curement organizations to transplant centers.

4 “(9) The Network shall work actively to in-
5 crease the supply of donated organs.

6 “(10) The Network shall recognize the dif-
7 ferences in health and in organ transplantation
8 issues between children and adults throughout the
9 system and adopt criteria, policies, and procedures
10 that address the unique health care needs of chil-
11 dren.

12 “(c) SCIENTIFIC REGISTRY.—

13 “(1) IN GENERAL.—The Network shall main-
14 tain a scientific registry of patients awaiting organ
15 transplantation, persons from whom organs are re-
16 moved for transplantation, and organ transplant re-
17 cipients for the ongoing evaluation of the scientific
18 and clinical status of organ transplantation.

19 “(2) REPORTS.—The Network shall prepare for
20 inclusion in the report under section 375 an analysis
21 of scientifically and clinically valid information de-
22 rived from the scientific registry under paragraph
23 (1).

24 “(d) INFORMATION AND DATA.—

25 “(1) IN GENERAL.—The Network shall—

1 “(A) provide information to physicians and
2 other health professionals regarding organ do-
3 nation and transplantation; and

4 “(B) collect, analyze, and annually publish
5 data concerning organ donation and transplan-
6 tation.

7 “(2) INFORMATION FOR PATIENTS AND GEN-
8 ERAL PUBLIC.—The Network shall make available to
9 patients in need of organ transplants information in
10 accordance with the following:

11 “(A) The information shall be transplant-
12 related information specific to transplant cen-
13 ters that are Network participants, which infor-
14 mation has been determined by the Network to
15 be scientifically and clinically valid.

16 “(B) The information shall be designed to
17 assist patients and referring physicians in
18 choosing a transplant center, including informa-
19 tion on the supply of and demand for organs.

20 “(C) With respect to the patient involved,
21 the information shall (taking into account pa-
22 tients in similar medical circumstances) include
23 the following as applied to specific transplant
24 centers:

1 “(i) The probability of receiving an
2 organ transplant.

3 “(ii) The length of time that similarly
4 situated patients have waited historically to
5 receive a transplant.

6 “(iii) Medical outcomes for similarly
7 situated patients, which information shall
8 be adjusted to reflect the medical risk fac-
9 tors for such patients.

10 “(D) With respect to the patient involved,
11 the information shall include the information
12 described in subparagraph (C) as applied to the
13 service areas of specific qualified organ procure-
14 ment organizations (other than such areas in
15 which there is only one transplant center).

16 “(E) Information under this paragraph
17 shall be updated not less frequently than once
18 a year.

19 “(3) ANNUAL PUBLIC REPORT.—The Network
20 shall annually make available to the public a report
21 on the overall status of organ procurement and
22 transplantation.

23 “(4) CONFIDENTIALITY.—Except for the re-
24 lease of information that is authorized under para-
25 graph (2) or (3) by the Network, neither the Net-

1 work nor the Secretary has authority to release the
2 following information (unless authorized in writing
3 by the patient or other entity with which the data
4 is concerned):

5 “(A) Information that permits direct or in-
6 direct identification of any patient who is wait-
7 ing for a transplant, or who is an organ trans-
8 plant patient or recipient of an organ.

9 “(B) Information that permits direct or in-
10 direct identification of any potential or actual
11 organ donors.

12 “(C) Information that permits direct or in-
13 direct identification of participants in Network
14 deliberations or determinations related to prac-
15 titioner or institutional qualifications, due proc-
16 ess proceedings or peer review activities, except
17 for information announcing final decisions of
18 the Network.

19 This paragraph may not be construed as prohibiting
20 the disclosure of information within the Network, in-
21 cluding information disclosed in the course of inter-
22 active organ sharing operations within the Network.

23 “(e) STUDIES.—

24 “(1) IN GENERAL.—The Network shall carry
25 out studies and demonstration projects for the pur-

1 pose of improving procedures for organ procurement
2 and allocation, including but not limited to projects
3 to examine and attempt to increase transplantation
4 among populations with special needs or limited ac-
5 cess to transplantation, and among children.

6 “(2) CERTAIN TECHNOLOGIES.—The Network
7 may study the impact of possible transplantation of
8 animal organs (xenotransplantation) and other tech-
9 nologies to determine the impact upon, and prevent
10 negative effects on, the fair and effective use of
11 human allograft organs.

12 “(f) QUALITY ASSURANCE; MONITORING OF NET-
13 WORK PARTICIPANTS.—The Network shall monitor the
14 operations of Network participants to the extent appro-
15 priate for determining whether the participants are main-
16 taining compliance with criteria under subsection (b)(3).
17 In monitoring a Network participant under the preceding
18 sentence, the Network shall inform the participant of any
19 findings indicating noncompliance by the participant.

20 “(g) QUALITY ASSURANCE; PEER REVIEW PRO-
21 CEEDINGS.—

22 “(1) IN GENERAL.—The Network shall develop
23 a peer review system for assuring that members of
24 the Network comply with criteria under subsection
25 (b)(3).

1 “(2) NONCOMPLIANCE.—

2 “(A) PAYMENT OF DAMAGES.—The Net-
3 work shall require that, as a condition of being
4 a Network participant, each such participant
5 agree that the Network may, through a peer re-
6 view proceeding under paragraph (1), require
7 the participant to pay damages for the failure
8 of the participant to comply with criteria under
9 subsection (b)(3). The Network shall establish
10 procedures to ensure that such proceedings are
11 conducted in an impartial manner, with ade-
12 quate opportunity for the Network participant
13 involved to receive a hearing. The Network shall
14 identify various types of violations of such cri-
15 teria and specify the maximum amount of dam-
16 ages that the Network may under this subpara-
17 graph require a Network participant to pay for
18 the type of violation involved.

19 “(B) RESTRICTING ACCESS TO ALLOCA-
20 TION SYSTEM.—If under subparagraph (A) it
21 has been determined that a Network participant
22 has engaged in substantial violations of criteria
23 under subsection (b)(3), the Network may re-
24 strict the extent to which such participant is

1 permitted to receive allocations of organs
2 through the Network.

3 “(C) STATUS OF NETWORK PARTICIPANTS
4 WITH RESPECT TO VIOLATIONS.—Subject to
5 paragraph (3), the Network may take actions to
6 make the public aware of the extent to which a
7 Network participant has been required to pay
8 damages under subparagraph (A) or has been
9 the subject of restrictions under subparagraph
10 (B).

11 “(3) CONFIDENTIALITY.—With respect to a
12 peer review proceeding under paragraph (1), neither
13 the Network nor the Secretary has authority to re-
14 lease data or information to the public relating to
15 the proceedings without the written permission of all
16 the parties involved, except that if damages under
17 paragraph (2) are required to be paid, the require-
18 ment may be publicly announced after the conclusion
19 of the proceeding.

20 “(h) ADMINISTRATIVE PROVISIONS.—

21 “(1) LIMITATION ON AMOUNT OF CONTRACT.—
22 The amount provided under a contract under sub-
23 section (a) in any fiscal year may not exceed
24 \$6,000,000 for the operation of the Network, includ-
25 ing the scientific registry under subsection (c). Such

1 limitation does not apply to amounts provided under
2 the contract for increasing organ donation and pro-
3 curement.

4 “(2) RELATIONSHIP BETWEEN SECRETARY AND
5 NETWORK.—The administrative and procedural
6 functions described in this section for the Network
7 shall be carried out in accordance with the mutual
8 agreement of the Secretary and the Network. For
9 purposes of the preceding sentence, functions that
10 are scientific, clinical, or medical in nature are not
11 administrative or procedural functions and are with-
12 in the sole discretion of the Network. With respect
13 to the programs under titles XVIII and XIX of the
14 Social Security Act, this section may not be con-
15 strued as having any legal effect on such programs,
16 except to the extent that section 1138 of such Act,
17 or any other provision of such Act, provides other-
18 wise.

19 “(3) NONFEDERAL ASSETS OF NETWORK.—

20 “(A) IN GENERAL.—No assets in the pos-
21 session of the Network or revenues collected by
22 the Network, other than amounts appropriated
23 under section 378, shall be considered or be
24 treated as Federal property, Federal revenues,
25 or program funds pursuant to a Federal con-

1 tract, nor shall such assets, revenues, or non-
2 appropriated funds be subject to restriction or
3 control by the Secretary, nor shall any member
4 of the Network be required by the Secretary to
5 pay any fees to the Network, nor shall the Sec-
6 retary be authorized to collect or authorize col-
7 lection of service fees with respect to the Net-
8 work or the scientific registry under subsection
9 (c).

10 “(B) GIFTS.—This section does not pro-
11 hibit the Network from accepting gifts of money
12 or services, including gifts to carry out activities
13 to provide for an increase in the rate of organ
14 donation.

15 “(4) COMMUNITY ENDORSEMENT OF CONTRACT
16 RECIPIENT.—In the case of any contract under sub-
17 section (a) that is awarded after the date of the en-
18 actment of the Organ Procurement and Transplan-
19 tation Network Amendments of 2000, the Secretary
20 shall select an applicant to receive the contract from
21 among applicants that have the written endorsement
22 of a majority of the combined total number of trans-
23 plant centers and qualified organ procurement orga-
24 nizations that are Network participants (without re-

1 gard to whether such centers or organizations en-
2 dorse more than one applicant for the contract).

3 “(5) CHANGE IN CONTRACT RECIPIENT.—With
4 respect to the expiration of the period during which
5 a contract under subsection (a) is in effect, if the
6 Secretary makes a determination to award the con-
7 tract to a different entity than the entity to which
8 the previous contract under such subsection was
9 awarded, the Secretary shall publish in the Federal
10 Register a notice that such change in the adminis-
11 tration of the Network will take place, and the
12 change may not take effect any sooner than the ex-
13 piration of the 6-month period beginning on the date
14 on which the notice is so published. Such a change
15 does not affect the membership status of any Net-
16 work participant, or the membership status of any
17 individual who serves on the Board (other than any
18 membership position that is predicated solely on
19 being a representative of the current contractor
20 under subsection (a)).

21 “(i) ADDITIONAL PROCEDURES REGARDING OVER-
22 SIGHT AND PUBLIC ACCOUNTABILITY.—For purposes of
23 providing oversight of and public accountability for the op-
24 eration of the Network, the Secretary shall establish pro-
25 cedures for—

1 “(1) conducting public hearings and receiving
2 from interested persons comments regarding criteria
3 of the Network and critical comments relating to the
4 manner in which the Network is carrying out its du-
5 ties under this section;

6 “(2) providing such comments to the Network
7 and receiving responses from the Network; and

8 “(3) the consideration by the Secretary of such
9 comments.

10 “(j) EVALUATIONS BY GENERAL ACCOUNTING OF-
11 FICE.—

12 “(1) IN GENERAL.—The Comptroller General of
13 the United States shall periodically conduct evalua-
14 tions of the Network, including the structure and
15 function of the Network and the relationship be-
16 tween the Secretary and the nonprofit private entity
17 that under subsection (a) operates the Network. The
18 first such evaluation shall be completed not later
19 than 1 year after the date of the enactment of the
20 Organ Procurement and Transplantation Network
21 Amendments of 2000, and such an evaluation shall
22 be completed not later than every second year there-
23 after.

24 “(2) INPUT FROM FIELD.—In conducting eval-
25 uations under paragraph (1), the Comptroller Gen-

1 eral shall consult with organizations that represent
2 transplant surgeons, transplant physicians, trans-
3 plant centers, and qualified organ procurement orga-
4 nizations, and with other experts in the field of
5 organ transplantation, including experts who are not
6 members of the Board of the Network or of the ex-
7 ecutive structure of the contractor under subsection
8 (a) .

9 “(3) PROCEDURES OF NETWORK.—The Net-
10 work shall establish procedures for coordinating with
11 the Comptroller General for purposes of evaluations
12 under paragraph (1).

13 “(4) REPORTS TO CONGRESS.—

14 “(A) COMPTROLLER GENERAL.—The
15 Comptroller General shall prepare reports de-
16 scribing the findings of evaluations under para-
17 graph (1) and shall submit such reports to the
18 Committee on Commerce of the House of Rep-
19 resentatives and the Committee on Health,
20 Education, Labor, and Pensions of the Senate.
21 The Comptroller General shall provide a copy of
22 each such report to the Network.

23 “(B) NETWORK.—Not later than 180 days
24 after the date on which a report is submitted
25 under subparagraph (A), the Network shall

1 submit to each of the committees specified in
2 such subparagraph a report describing any ac-
3 tions the Network has taken in response to the
4 report under subparagraph (A).”.

5 (b) **RULE OF CONSTRUCTION.**—The amendments
6 made by this Act may not be construed as affecting the
7 duration of the contract under section 372 of the Public
8 Health Service Act that was in effect on the day before
9 the date of the enactment of this Act.

10 **SEC. 4. ADDITIONAL AMENDMENTS.**

11 (a) **IN GENERAL.**—Part H of title III of the Public
12 Health Service Act (42 U.S.C. 273 et seq.) is amended—

13 (1) by striking section 373;

14 (2) in section 374—

15 (A) in subsection (b)(1), by inserting after
16 “organization” the following: “and other orga-
17 nizations for the purpose of increasing the sup-
18 ply of transplantable organs”;

19 (B) in subsection (c), by striking “or 373”
20 each place such term appears; and

21 (C) in subsection (d), by amending para-
22 graph (2) to read as follows:

23 “(2) The term ‘organ’, with respect to trans-
24 plantation into humans, means the human or other
25 animal kidney, liver, heart, lung, pancreas, and any

1 other organ (other than human corneas and eyes)
2 specified by the Secretary by regulation. For pur-
3 poses of section 372(c), such term includes bone
4 marrow.”;

5 (3) in section 375—

6 (A) in paragraph (1), by striking “this
7 part” and inserting “this section”; and

8 (B) in paragraph (4)—

9 (i) by redesignating clauses (i) and
10 (ii) as subparagraphs (A) and (B), respec-
11 tively; and

12 (ii) in subparagraph (B) (as so redesi-
13 gnated), by striking “comparative costs
14 and patient outcomes” and inserting “com-
15 parative patient outcomes”;

16 (4) in section 376—

17 (A) by striking “the Secretary” and insert-
18 ing “the Organ Procurement and Transplan-
19 tation Network under section 372”; and

20 (B) by striking “Committee on Energy and
21 Commerce” and inserting “Committee on Com-
22 merce”; and

23 (5) by striking section 377.

24 (b) REDESIGNATIONS.—Part H of title III of the
25 Public Health Service Act, as amended by subsection (a)

1 of this section, is amended by redesignating sections 374
2 through 376 as sections 373 through 375, respectively.

3 (c) PERFORMANCE STANDARDS.—Section 371(b)(1)
4 of the Public Health Service Act (42 U.S.C. 273(b)(1))
5 is amended—

6 (1) by redesignating subparagraphs (D)
7 through (G) as subparagraphs (E) through (H), re-
8 spectively;

9 (2) by moving subparagraph (F) (as so redesign-
10 nated) two ems to the left; and

11 (3) by inserting after subparagraph (C) the fol-
12 lowing:

13 “(D) notwithstanding any other provision of
14 law, has met the other requirements of this sub-
15 section and has been certified or recertified by the
16 Secretary as meeting the performance standards to
17 be a qualified organ procurement organization
18 through a process which—

19 “(i) granted certification or recertification
20 within the previous 4 years with such certifi-
21 cation in effect as of October 1, 1999, and re-
22 maining in effect through the earlier of—

23 “(I) January 1, 2002; or

24 “(II) the completion of recertification
25 under the requirements of clause (ii); or

1 “(ii) is defined through regulations pro-
2 mulgated by the Secretary not later than Janu-
3 ary 1, 2002, which—

4 “(I) require recertifications of quali-
5 fied organ procurement organizations not
6 more frequently than once every 4 years;

7 “(II) rely on performance measures
8 that are based on empirical evidence of
9 organ donor potential and other related
10 factors in each service area of qualified
11 organ procurement organizations;

12 “(III) provide for the filing and ap-
13 proval of a corrective action plan by a
14 qualified organ procurement organization
15 that fails to meet the performance stand-
16 ards and a grace period of not less than 3
17 years during which such organization can
18 implement the corrective action plan with-
19 out risk of decertification; and

20 “(IV) provide for a qualified organ
21 procurement organization to appeal a de-
22 certification to the Secretary on sub-
23 stantive and procedural grounds;”.

1 **SEC. 5. PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES**
2 **INCURRED TOWARD LIVING ORGAN DONA-**
3 **TION.**

4 Part H of title III of the Public Health Service Act,
5 as amended by section 4(b) of this Act, is amended by
6 inserting after section 375 the following section:

7 “PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES
8 INCURRED TOWARD LIVING ORGAN DONATION

9 “SEC. 376. (a) IN GENERAL.—The Secretary may
10 make awards of grants or contracts to States, transplant
11 centers, qualified organ procurement organizations under
12 section 371, or other public or private entities for the pur-
13 pose of—

14 “(1) providing for the payment of travel and
15 subsistence expenses incurred by individuals toward
16 making living donations of their organs (in this sec-
17 tion referred as ‘donating individuals’); and

18 “(2) in addition, providing for the payment of
19 such incidental nonmedical expenses that are so in-
20 curred as the Secretary determines by regulation to
21 be appropriate.

22 “(b) ELIGIBILITY.—

23 “(1) IN GENERAL.—Payments under subsection
24 (a) may be made for the qualifying expenses of a do-
25 nating individual only if—

1 “(A) the State in which the donating indi-
2 vidual resides is a different State than the
3 State in which the intended recipient of the
4 organ resides; and

5 “(B) the annual income of the intended re-
6 cipient of the organ does not exceed \$35,000
7 (as adjusted for fiscal year 2001 and subse-
8 quent fiscal years to offset the effects of infla-
9 tion occurring after the beginning of fiscal year
10 2000).

11 “(2) CERTAIN CIRCUMSTANCES.—Subject to
12 paragraph (1), the Secretary may in carrying out
13 subsection (a) provide as follows:

14 “(A) The Secretary may consider the term
15 ‘donating individuals’ as including individuals
16 who in good faith incur qualifying expenses to-
17 ward the intended donation of an organ but
18 with respect to whom, for such reasons as the
19 Secretary determines to be appropriate, no do-
20 nation of the organ occurs.

21 “(B) The Secretary may consider the term
22 ‘qualifying expenses’ as including the expenses
23 of having one or more family members of do-
24 nating individuals accompany the donating indi-
25 viduals for purposes of subsection (a) (subject

1 to making payment for only such types of ex-
2 penses as are paid for donating individuals).

3 “(c) LIMITATION ON AMOUNT OF PAYMENT.—

4 “(1) IN GENERAL.—With respect to the geo-
5 graphic area to which a donating individual travels
6 for purposes of subsection (a), if such area is other
7 than the covered vicinity for the intended recipient
8 of the organ, the amount of qualifying expenses for
9 which payments under such subsection are made
10 may not exceed the amount of such expenses for
11 which payment would have been made if such area
12 had been the covered vicinity for the intended recipi-
13 ent, taking into account the costs of travel and re-
14 gional differences in the costs of living.

15 “(2) COVERED VICINITY.—For purposes of this
16 section, the term ‘covered vicinity’, with respect to
17 an intended recipient of an organ from a donating
18 individual, means the vicinity of the nearest trans-
19 plant center to the residence of the intended recipi-
20 ent that regularly performs transplants of that type
21 of organ.

22 “(d) RELATIONSHIP TO PAYMENTS UNDER OTHER
23 PROGRAMS.—An award may be made under subsection (a)
24 only if the applicant involved agrees that the award will
25 not be expended to pay the qualifying expenses of a donat-

1 ing individual to the extent that payment has been made,
2 or can reasonably be expected to be made, with respect
3 to such expenses—

4 “(1) under any State compensation program,
5 under an insurance policy, or under any Federal or
6 State health benefits program; or

7 “(2) by an entity that provides health services
8 on a prepaid basis.

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

10 “(1) The term ‘covered vicinity’ has the mean-
11 ing given such term in subsection (c)(2).

12 “(2) The term ‘donating individuals’ has the
13 meaning indicated for such term in subsection
14 (a)(1), subject to subsection (b)(2)(A).

15 “(3) The term ‘qualifying expenses’ means the
16 expenses authorized for purposes of subsection (a),
17 subject to subsection (b)(2)(B).

18 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
19 purpose of carrying out this section, there is authorized
20 to be appropriated \$5,000,000 for each of the fiscal years
21 2000 through 2005.”.

1 **SEC. 6. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.**
2

3 Part H of title III of the Public Health Service Act,
4 as amended by section 5 of this Act, is amended by insert-
5 ing after section 376 the following section:

6 “PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS

7 “SEC. 377. (a) PUBLIC AWARENESS.—The Secretary
8 shall (directly or through grants or contracts) carry out
9 a program to educate the public with respect to organ do-
10 nation, including the need to provide for an adequate rate
11 of such donations.

12 “(b) STUDIES AND DEMONSTRATIONS.—The Sec-
13 retary may make grants to public and nonprofit private
14 entities for the purpose of carrying out studies and dem-
15 onstration projects with respect to providing for an ade-
16 quate rate of organ donation.

17 “(c) GRANTS TO STATES.—The Secretary may make
18 grants to States for the purpose of assisting States in car-
19 rying out organ donor awareness, public education and
20 outreach activities and programs designed to increase the
21 number of organ donors within the State, including living
22 donors. To be eligible, each State shall—

23 “(1) submit an application to the Department
24 in the form prescribed;

25 “(2) establish yearly benchmarks for improve-
26 ment in organ donation rates in the State;

1 “(3) develop, enhance or expand a State donor
2 registry, which shall be available to hospitals, organ
3 procurement organizations, and other States upon a
4 search request; and

5 “(4) report to the Secretary on an annual basis
6 a description and assessment of the State’s use of
7 these grant funds, accompanied by an assessment of
8 initiatives for potential replication in other States.

9 Funds may be used by the State or in partnership with
10 other public agencies or private sector institutions for edu-
11 cation and awareness efforts, information dissemination,
12 activities pertaining to the State organ donor registry, and
13 other innovative donation specific initiatives, including liv-
14 ing donation.

15 “(d) ANNUAL REPORT TO CONGRESS.—The Sec-
16 retary shall annually submit to the Congress a report on
17 the activities carried out under this section, including pro-
18 visions describing the extent to which the activities have
19 affected the rate of organ donation.

20 “(e) AUTHORIZATION OF APPROPRIATIONS.—

21 “(1) IN GENERAL.—For the purpose of car-
22 rying out this section, there are authorized to be ap-
23 propriated \$15,000,000 for fiscal year 2000, and
24 such sums as may be necessary for each of the fiscal
25 years 2001 through 2005. Such authorization of ap-

1 appropriations is in addition to any other authoriza-
2 tions of appropriations that is available for such
3 purpose.

4 “(2) STUDIES AND DEMONSTRATIONS.—Of the
5 amounts appropriated under paragraph (1) for a fis-
6 cal year, the Secretary may not obligate more than
7 \$2,000,000 for carrying out subsection (b).”.

8 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

9 Section 378 of the Public Health Service Act (42
10 U.S.C. 274g) is amended to read as follows:

11 “AUTHORIZATION OF APPROPRIATIONS FOR ORGAN
12 PROCUREMENT AND TRANSPLANTATION NETWORK

13 “SEC. 378. (a) OPERATION OF NETWORK.—For the
14 purpose of providing for the Organ Procurement and
15 Transplantation Network under section 372, including the
16 scientific registry, there are authorized to be appropriated
17 \$6,000,000 for fiscal year 2000, and such sums as may
18 be necessary for each of the fiscal years 2001 through
19 2005.

20 “(b) INCREASING ORGAN DONATION AND PROCURE-
21 MENT.—For the purpose of increasing organ donation and
22 procurement through the Organ Procurement and Trans-
23 plantation Network under section 372, there are author-
24 ized to be appropriated such sums as may be necessary
25 for each of the fiscal years 2000 through 2005. Such au-
26 thorization of appropriations is with respect to such pur-

1 pose in addition to the authorization of appropriations es-
2 tablished in subsection (a).”.

3 **SEC. 8. STUDY REGARDING IMMUNOSUPPRESSIVE DRUGS.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services (referred to in this section as the “Sec-
6 retary”) shall provide for a study to determine the costs
7 of immunosuppressive drugs that are provided to children
8 pursuant to organ transplants and to determine the extent
9 to which health plans and health insurance cover such
10 costs. The Secretary may carry out the study directly or
11 through a grant to the Institute of Medicine (or other pub-
12 lic or nonprofit private entity).

13 (b) RECOMMENDATIONS REGARDING CERTAIN
14 ISSUES.—The Secretary shall ensure that, in addition to
15 making determinations under subsection (a), the study
16 under such subsection makes recommendations regarding
17 the following issues:

18 (1) The costs of immunosuppressive drugs that
19 are provided to children pursuant to organ trans-
20 plants and to determine the extent to which health
21 plans, health insurance and Government programs
22 cover such costs.

23 (2) The extent of denial of organs to be re-
24 leased for transplant by coroners and medical exam-
25 iners.

1 (3) The special growth and developmental
2 issues that children have pre- and post-organ trans-
3 plantation.

4 (4) Other issues that are particular to the spe-
5 cial health and transplantation needs of children.

6 (c) REPORT.—The Secretary shall ensure that, not
7 later than December 31, 2000, the study under subsection
8 (a) is completed and a report describing the findings of
9 the study is submitted to the Congress.

10 **SEC. 9. NULLIFICATION OF FINAL RULE RELATING TO**
11 **ORGAN PROCUREMENT AND TRANSPLAN-**
12 **TATION NETWORK.**

13 Notwithstanding any other provision of law, the final
14 rule relating to the Organ Procurement and Transplan-
15 tation Network, promulgated by the Secretary of Health
16 and Human Services and published in the Federal Reg-
17 ister on April 2, 1998 (63 Fed. Reg. 16296 et seq. adding
18 part 121 to title 42, Code of Federal Regulations) and
19 amended on October 20, 1999 (64 Fed. Reg. 56649 et
20 seq.), shall have no force or legal effect.

1 **SEC. 10. EFFECTIVE DATE.**

2 The amendments made by this Act take effect Octo-
3 ber 1, 1999, or upon the date of the enactment of this
4 Act, whichever occurs later.

 Passed the House of Representatives April 4, 2000.

Attest:

Clerk.

106TH CONGRESS
2D SESSION

H. R. 2418

AN ACT

To amend the Public Health Service Act to revise and extend programs relating to organ procurement and transplantation.