

Union Calendar No. 250

106TH CONGRESS
1ST SESSION

H. R. 2418

[Report No. 106-429]

A BILL

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

NOVEMBER 1, 1999

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

Union Calendar No. 250

106TH CONGRESS
1ST SESSION

H. R. 2418

[Report No. 106-429]

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

IN THE HOUSE OF REPRESENTATIVES

JULY 1, 1999

Mr. BILIRAKIS (for himself, Mr. GREEN of Texas, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Commerce

NOVEMBER 1, 1999

Additional sponsors: Mr. JEFFERSON, Mr. FROST, Mr. BENTSEN, Ms. JACKSON-LEE of Texas, Mr. DEUTSCH, Mr. WALDEN of Oregon, Mr. BACHUS, Mr. KLECZKA, Mr. WHITFIELD, Mr. GOODE, Mr. TAUZIN, Mr. FOLEY, Mr. DEAL of Georgia, Mr. DEFAZIO, Mr. BAKER, Mr. CUNNINGHAM, Mr. COOKSEY, Mr. HINCHEY, Mr. ROMERO-BARCELO, Mr. COBURN, Mr. CRAMER, Mr. RILEY, Mr. VITTER, Mr. WATTS of Oklahoma, Mr. LARGENT, Mr. HILLIARD, Mr. HALL of Texas, Mr. ISTOOK, Mr. JOHN, Mr. MCCRERY, Mr. CALLAHAN, Mrs. KELLY, Mr. GILMAN, Mr. DEMINT, Mrs. NORTHUP, Mr. GRAHAM, Mr. CLEMENT, Mr. GORDON, Mrs. ROUKEMA, Mr. WU, Mr. LATHAM, Mr. BRYANT, Mr. NORWOOD, Ms. MCKINNEY, Mr. FRANKS of New Jersey, Mr. SPRATT, Mr. GANSKE, Mr. SPENCE, Mr. CLYBURN, Mr. FLETCHER, Ms. BALDWIN, Mr. WATKINS, Mr. PICKETT, Mr. WAMP, Mr. BLUNT, Mr. CHAMBLISS, Mr. LEWIS of Georgia, Mr. DICKS, Mr. ROTHMAN, Mrs. THURMAN, Mr. BOYD, Mr. MATSUI, Mr. OXLEY, Mr. DUNCAN, Mr. TANNER, Mr. ROGERS, Mr. FRELINGHUYSEN, Mr. SANFORD, Mrs. MINK of Hawaii, Mr. LOBIONDO, Mr. MENENDEZ, Mr. SMITH of New Jersey, Mr. ANDREWS, Mr. PASCARELL, Mr. PAYNE, Mr. SAXTON, Mr. HOLT, Mr. LINDER, Ms. RIVERS, Mr. JENKINS, Mr. HILLEARY, Mr. NETHERCUTT, Mr. WELDON of Florida, and Mr. CANADY of Florida

NOVEMBER 1, 1999

Reported with an amendment, committed to the Committee of the Whole
House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on July 1, 1999]

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Organ Procurement and*
5 *Transplantation Network Amendments of 1999”.*

6 **SEC. 2. FINDINGS.**

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

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

1 (2) *The Organ Procurement and Transplan-*
2 *tation Network (“Network”), which was established in*
3 *the private sector pursuant to a contract awarded by*
4 *the Federal Government, should continue to be oper-*
5 *ated by a nonprofit private entity pursuant to a con-*
6 *tract with the Federal Government.*

7 (3) *The Federal Government should continue to*
8 *provide Federal oversight of and financial assistance*
9 *for the services provided by the Network.*

10 (4) *The responsibility for developing, estab-*
11 *lishing, and maintaining medical criteria and stand-*
12 *ards for organ procurement and transplantation be-*
13 *longs in the private sector and is a function of the*
14 *Network.*

15 (5) *The Federal Government should assist the ef-*
16 *forts of the Network to serve patient and donor fami-*
17 *lies in procuring and distributing organs.*

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

22 (b) *SENSE OF CONGRESS REGARDING FAMILY DISCUS-*
23 *SIONS OF ORGAN DONATIONS.—The Congress recognizes the*
24 *importance of families pledging to each other to share their*
25 *lives as organ and tissue donors and acknowledges the im-*

1 *portance of discussing organ and tissue donation as a fam-*
 2 *ily.*

3 (c) *SENSE OF CONGRESS REGARDING LIVING DONA-*
 4 *TIONS OF ORGANS.—The Congress—*

5 (1) *recognizes the generous contribution made by*
 6 *each living individual who has donated an organ to*
 7 *save a life; and*

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

13 **SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION**
 14 **NETWORK.**

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

17 “*ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK*

18 “*SEC. 372. (a) IN GENERAL.—The Secretary shall by*
 19 *contract provide for the continuing operation of an Organ*
 20 *Procurement and Transplantation Network (in this section*
 21 *referred to as the ‘Network’), which contract shall be award-*
 22 *ed to a nonprofit private entity that has expertise and expe-*
 23 *rience in organ procurement and transplantation. The Net-*
 24 *work shall meet the following requirements:*

1 “(1) *The Network shall be an independent, non-*
2 *profit private entity that is a separate legal entity*
3 *from the entity to which such contract is awarded.*

4 “(2) *The Network shall in accordance with cri-*
5 *teria under subsection (b)(3) include as members*
6 *qualified organ procurement organizations (as de-*
7 *scribed in section 371(b)), transplant centers, and*
8 *other entities that have a demonstrated interest in the*
9 *fields of organ donation or transplantation. (Such*
10 *members are in this section referred to as ‘Network*
11 *participants’.)*

12 “(3) *The Network shall have a board of directors*
13 *(in this section referred to as the ‘Board’). The Board*
14 *shall, after consultation with Network participants,*
15 *establish the policies for carrying out the functions*
16 *described in this section for the Network.*

17 “(4) *The Board shall be in accordance with the*
18 *following:*

19 “(A) *The Board shall include representa-*
20 *tives of qualified organ procurement organiza-*
21 *tions, transplant centers, voluntary health asso-*
22 *ciations, and the general public, including a rea-*
23 *sonable proportion of the members of the Board*
24 *who are patients awaiting a transplant or trans-*
25 *plant recipients or individuals who have donated*

1 *an organ or family members of patients, recipi-*
2 *ents or donors.*

3 “(B) *The Board shall establish membership*
4 *categories and qualifications with respect to serv-*
5 *ing on the Board, and shall have exclusive au-*
6 *thority to admit individuals to membership on*
7 *the Board. Transplant surgeons and transplant*
8 *physicians shall comprise not less than 50 per-*
9 *cent of the membership of the Board. The Board*
10 *shall be limited to a total of 42 members.*

11 “(C) *The Board shall have an executive*
12 *committee, and such other committees as the*
13 *Board determines to be appropriate.*

14 “(D) *The chair of each such committee shall*
15 *be selected so as to ensure the continuity of lead-*
16 *ership for the Board.*

17 “(b) *GENERAL FUNCTIONS.—The following applies to*
18 *the Network:*

19 “(1) *The Network shall establish and operate a*
20 *national system to match organs and individuals who*
21 *need organ transplants, especially individuals whose*
22 *immune system makes it difficult for them to receive*
23 *organs.*

24 “(2) *The national system shall maintain one or*
25 *more lists of individuals who need organ transplants,*

1 *shall be operated in accordance with established med-*
2 *ical criteria, shall be operated through the use of com-*
3 *puters, and may function on a regionalized basis.*

4 “(3) *The Network shall establish criteria for*
5 *being a Network participant, shall establish medical*
6 *criteria for listing patients and for allocating organs,*
7 *and shall provide to members of the public an oppor-*
8 *tunity to comment with respect to such criteria.*

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

12 “(5) *The Network shall assist organ procurement*
13 *organizations in the distribution of organs. The dis-*
14 *tribution of organs shall be based on medical criteria*
15 *established by the Network, and also shall be based on*
16 *equity and ethics without regard to economic status*
17 *of those awaiting organ transplants and without po-*
18 *litical control or influence.*

19 “(6) *The Network shall adopt and use standards*
20 *of quality for the acquisition and transportation of*
21 *donated organs, including standards regarding the*
22 *transmission of infectious diseases.*

23 “(7) *The Network shall prepare and distribute,*
24 *on a regionalized basis (and, to the extent practicable,*
25 *among regions or on a national basis), samples of*

1 *blood sera from individuals who are included on the*
2 *list and whose immune system makes it difficult for*
3 *them to receive organs, in order to facilitate matching*
4 *the compatibility of such individuals with organ do-*
5 *nors.*

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

9 “(9) *The Network shall work actively to increase*
10 *the supply of donated organs.*

11 “(10) *The Network shall establish criteria, poli-*
12 *cies, and procedures to address the disparity in mor-*
13 *tality rates between children and adults while waiting*
14 *for organ transplants.*

15 “(c) *SCIENTIFIC REGISTRY.—*

16 “(1) *IN GENERAL.—The Network shall maintain*
17 *a scientific registry of patients awaiting organ trans-*
18 *plantation, persons from whom organs are removed*
19 *for transplantation, and organ transplant recipients*
20 *for the ongoing evaluation of the scientific and clin-*
21 *ical status of organ transplantation.*

22 “(2) *REPORTS.—The Network shall prepare for*
23 *inclusion in the report under section 375 an analysis*
24 *of scientifically and clinically valid information de-*

1 *rived from the scientific registry under paragraph*
2 *(1).*

3 *“(d) INFORMATION AND DATA.—*

4 *“(1) IN GENERAL.—The Network shall—*

5 *“(A) provide information to physicians and*
6 *other health professionals regarding organ dona-*
7 *tion and transplantation; and*

8 *“(B) collect, analyze, and annually publish*
9 *data concerning organ donation and transplan-*
10 *tation.*

11 *“(2) INFORMATION FOR PATIENTS AND GENERAL*
12 *PUBLIC.—The Network shall make available to pa-*
13 *tients in need of organ transplants information in ac-*
14 *cordance with the following:*

15 *“(A) The information shall be transplant-*
16 *related information specific to transplant centers*
17 *that are Network participants, which informa-*
18 *tion has been determined by the Network to be*
19 *scientifically and clinically valid.*

20 *“(B) The information shall be designed to*
21 *assist patients and referring physicians in choos-*
22 *ing a transplant center, including information*
23 *on the supply of and demand for organs.*

24 *“(C) With respect to the patient involved,*
25 *the information shall (taking into account pa-*

1 *tients in similar medical circumstances) include*
2 *the following as applied to specific transplant*
3 *centers:*

4 “(i) *The probability of receiving an*
5 *organ transplant.*

6 “(ii) *The length of time that similarly*
7 *situated patients have waited historically to*
8 *receive a transplant.*

9 “(iii) *Medical outcomes for similarly*
10 *situated patients, which information shall*
11 *be adjusted to reflect the medical risk factors*
12 *for such patients.*

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

19 “(E) *Information under this paragraph*
20 *shall be updated not less frequently than once a*
21 *year.*

22 “(3) *ANNUAL PUBLIC REPORT.—The Network*
23 *shall annually make available to the public a report*
24 *on the overall status of organ procurement and trans-*
25 *plantation.*

1 “(4) *CONFIDENTIALITY.*—*Except for the release*
2 *of information that is authorized under paragraph*
3 *(2) or (3) by the Network, neither the Network nor the*
4 *Secretary has authority to release the following infor-*
5 *mation (unless authorized in writing by the patient*
6 *or other entity with which the data is concerned):*

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

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

14 “(C) *Information that permits direct or in-*
15 *direct identification of participants in Network*
16 *deliberations or determinations related to practi-*
17 *tioner or institutional qualifications, due process*
18 *proceedings or peer review activities, except for*
19 *information announcing final decisions of the*
20 *Network.*

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

25 “(e) *STUDIES.*—

1 “(1) *IN GENERAL.*—*The Network shall carry out*
2 *studies and demonstration projects for the purpose of*
3 *improving procedures for organ procurement and al-*
4 *location, including but not limited to projects to ex-*
5 *amine and attempt to increase transplantation*
6 *among populations with special needs or limited ac-*
7 *cess to transplantation, and among children.*

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

14 “(f) *QUALITY ASSURANCE; MONITORING OF NETWORK*
15 *PARTICIPANTS.*—*The Network shall monitor the operations*
16 *of Network participants to the extent appropriate for deter-*
17 *mining whether the participants are maintaining compli-*
18 *ance with criteria under subsection (b)(3). In monitoring*
19 *a Network participant under the preceding sentence, the*
20 *Network shall inform the participant of any findings indi-*
21 *cating noncompliance by the participant.*

22 “(g) *QUALITY ASSURANCE; PEER REVIEW PRO-*
23 *CEEDINGS.*—

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

4 “(2) *NONCOMPLIANCE.*—

5 “(A) *PAYMENT OF DAMAGES.*—*The Network*
6 *shall require that, as a condition of being a Net-*
7 *work participant, each such participant agree*
8 *that the Network may, through a peer review*
9 *proceeding under paragraph (1), require the par-*
10 *icipant to pay damages for the failure of the*
11 *participant to comply with criteria under sub-*
12 *section (b)(3). The Network shall establish proce-*
13 *dures to ensure that such proceedings are con-*
14 *ducted in an impartial manner, with adequate*
15 *opportunity for the Network participant involved*
16 *to receive a hearing. The Network shall identify*
17 *various types of violations of such criteria and*
18 *specify the maximum amount of damages that*
19 *the Network may under this subparagraph re-*
20 *quire a Network participant to pay for the type*
21 *of violation involved.*

22 “(B) *RESTRICTING ACCESS TO ALLOCATION*
23 *SYSTEM.*—*If under subparagraph (A) it has been*
24 *determined that a Network participant has en-*
25 *gaged in substantial violations of criteria under*

1 *subsection (b)(3), the Network may restrict the*
2 *extent to which such participant is permitted to*
3 *receive allocations of organs through the Net-*
4 *work.*

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

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

21 *“(h) ADMINISTRATIVE PROVISIONS.—*

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

1 *the scientific registry under subsection (c). Such limi-*
2 *tation does not apply to amounts provided under the*
3 *contract for increasing organ donation and procure-*
4 *ment.*

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

19 “(3) *NONFEDERAL ASSETS OF NETWORK.—*

20 “(A) *IN GENERAL.—No assets in the posses-*
21 *sion of the Network or revenues collected by the*
22 *Network, other than amounts appropriated*
23 *under section 378, shall be considered or be treat-*
24 *ed as Federal property, Federal revenues, or pro-*
25 *gram funds pursuant to a Federal contract, nor*

1 *shall such assets, revenues, or nonappropriated*
2 *funds be subject to restriction or control by the*
3 *Secretary, nor shall any member of the Network*
4 *be required by the Secretary to pay any fees to*
5 *the Network, nor shall the Secretary be author-*
6 *ized to collect or authorize collection of service*
7 *fees with respect to the Network or the scientific*
8 *registry under subsection (c).*

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

14 “(4) *COMMUNITY ENDORSEMENT OF CONTRACT*
15 *RECIPIENT.—In the case of any contract under sub-*
16 *section (a) that is awarded after the date of the enact-*
17 *ment of the Organ Procurement and Transplantation*
18 *Network Amendments of 1999, the Secretary shall se-*
19 *lect an applicant to receive the contract from among*
20 *applicants that have the written endorsement of a*
21 *majority of the combined total number of transplant*
22 *centers and qualified organ procurement organiza-*
23 *tions that are Network participants (without regard*
24 *to whether such centers or organizations endorse more*
25 *than one applicant for the contract).*

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

18 “(i) *ADDITIONAL PROCEDURES REGARDING OVER-*
19 *SIGHT AND PUBLIC ACCOUNTABILITY.*—For purposes of
20 *providing oversight of and public accountability for the op-*
21 *eration of the Network, the Secretary shall establish proce-*
22 *dures for—*

23 “(1) *conducting public hearings and receiving*
24 *from interested persons comments regarding criteria*
25 *of the Network and critical comments relating to the*

1 *manner in which the Network is carrying out its du-*
2 *ties under this section;*

3 *“(2) providing such comments to the Network*
4 *and receiving responses from the Network; and*

5 *“(3) the consideration by the Secretary of such*
6 *comments.*

7 *“(j) EVALUATIONS BY GENERAL ACCOUNTING OF-*
8 *FICE.—*

9 *“(1) IN GENERAL.—The Comptroller General of*
10 *the United States shall periodically conduct evalua-*
11 *tions of the Network, including the structure and*
12 *function of the Network and the relationship between*
13 *the Secretary and the nonprofit private entity that*
14 *under subsection (a) operates the Network. The first*
15 *such evaluation shall be completed not later than one*
16 *year after the date of the enactment of the Organ Pro-*
17 *curement and Transplantation Network Amendments*
18 *of 1999, and such an evaluation shall be completed*
19 *not later than every second year thereafter.*

20 *“(2) INPUT FROM FIELD.—In conducting evalua-*
21 *tions under paragraph (1), the Comptroller General*
22 *shall consult with organizations that represent trans-*
23 *plant surgeons, transplant physicians, transplant*
24 *centers, and qualified organ procurement organiza-*
25 *tions, and with other experts in the field of organ*

1 *transplantation, including experts who are not mem-*
2 *bers of the Board of the Network or of the executive*
3 *structure of the contractor under subsection (a) .*

4 “(3) *PROCEDURES OF NETWORK.—The Network*
5 *shall establish procedures for coordinating with the*
6 *Comptroller General for purposes of evaluations under*
7 *paragraph (1).*

8 “(4) *REPORTS TO CONGRESS.—*

9 “(A) *COMPTROLLER GENERAL.—The Comp-*
10 *troller General shall prepare reports describing*
11 *the findings of evaluations under paragraph (1)*
12 *and shall submit such reports to the Committee*
13 *on Commerce of the House of Representatives*
14 *and the Committee on Health, Education, Labor,*
15 *and Pensions of the Senate. The Comptroller*
16 *General shall provide a copy of each such report*
17 *to the Network.*

18 “(B) *NETWORK.—Not later than 180 days*
19 *after the date on which a report is submitted*
20 *under subparagraph (A), the Network shall sub-*
21 *mit to each of the committees specified in such*
22 *subparagraph a report describing any actions*
23 *the Network has taken in response to the report*
24 *under subparagraph (A).”.*

1 **(b) RULE OF CONSTRUCTION.**—*The amendments made*
2 *by this Act may not be construed as affecting the duration*
3 *of the contract under section 372 of the Public Health Serv-*
4 *ice Act that was in effect on the day before the date of the*
5 *enactment of this Act.*

6 **SEC. 4. ADDITIONAL AMENDMENTS.**

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

9 **(1)** *by striking section 373;*

10 **(2)** *in section 374—*

11 **(A)** *in subsection (b)(1), by inserting after*
12 *“organization” the following: “and other organi-*
13 *zations for the purpose of increasing the supply*
14 *of transplantable organs”;*

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

17 **(C)** *in subsection (d), by amending para-*
18 *graph (2) to read as follows:*

19 **(2)** *The term ‘organ’, with respect to transplan-*
20 *tation into humans, means the human or other ani-*
21 *mal kidney, liver, heart, lung, pancreas, and any*
22 *other organ (other than human corneas and eyes)*
23 *specified by the Secretary by regulation. For purposes*
24 *of section 372(c), such term includes bone marrow.”;*

25 **(3)** *in section 375—*

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

3 (B) in paragraph (4)—

4 (i) by redesignating clauses (i) and (ii)
5 as subparagraphs (A) and (B), respectively;
6 and

7 (ii) in subparagraph (B) (as so redesi-
8 gnated), by striking “comparative costs
9 and patient outcomes” and inserting “com-
10 parative patient outcomes”;

11 (4) in section 376—

12 (A) by striking “the Secretary” and insert-
13 ing “the Organ Procurement and Transplan-
14 tation Network under section 372”; and

15 (B) by striking “Committee on Energy and
16 Commerce” and inserting “Committee on Com-
17 merce”; and

18 (5) by striking section 377.

19 (b) *REDESIGNATIONS.*—Part H of title III of the Pub-
20 lic Health Service Act, as amended by subsection (a) of this
21 section, is amended by redesignating sections 374 through
22 376 as sections 373 through 375, respectively.

23 (c) *PERFORMANCE STANDARDS.*—Section 371(b)(1) of
24 the Public Health Service Act (42 U.S.C. 273(b)(1)) is
25 amended—

1 (1) by redesignating subparagraphs (D) through
2 (G) as subparagraphs (E) through (H), respectively;

3 (2) by moving subparagraph (F) (as so redesign-
4 ated) two ems to the left; and

5 (3) by inserting after subparagraph (C) the fol-
6 lowing:

7 “(D) notwithstanding any other provision of
8 law, has met the other requirements of this subsection
9 and has been certified or recertified by the Secretary
10 as meeting the performance standards to be a quali-
11 fied organ procurement organization through a proc-
12 ess which—

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

17 “(I) January 1, 2002, or

18 “(II) the completion of recertification
19 under the requirements of clause (ii); or

20 “(ii) is defined through regulations promul-
21 gated by the Secretary not later than January 1,
22 2002, which—

23 “(I) require recertifications of qualified
24 organ procurement organizations not more
25 frequently than once every 4 years;

1 “(II) rely on performance measures
2 that are based on empirical evidence of
3 organ donor potential and other related fac-
4 tors in each service area of qualified organ
5 procurement organizations;

6 “(III) provide for the filing and ap-
7 proval of a corrective action plan by a
8 qualified organ procurement organization
9 that fails to meet the performance standards
10 and a grace period of not less than 3 years
11 during which such organization can imple-
12 ment the corrective action plan without risk
13 of decertification; and

14 “(IV) provide for a qualified organ
15 procurement organization to appeal a decer-
16 tification to the Secretary on substantive
17 and procedural grounds;”.

18 **SEC. 5. PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES**
19 **INCURRED TOWARD LIVING ORGAN DONA-**
20 **TION.**

21 Part H of title III of the Public Health Service Act,
22 as amended by section 4(b) of this Act, is amended by in-
23 serting after section 375 the following section:

1 *“PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES*
2 *INCURRED TOWARD LIVING ORGAN DONATION*

3 *“SEC. 376. (a) IN GENERAL.—The Secretary may*
4 *make awards of grants or contracts to States, transplant*
5 *centers, qualified organ procurement organizations under*
6 *section 371, or other public or private entities for the pur-*
7 *pose of—*

8 *“(1) providing for the payment of travel and*
9 *subsistence expenses incurred by individuals toward*
10 *making living donations of their organs (in this sec-*
11 *tion referred as ‘donating individuals’); and*

12 *“(2) in addition, providing for the payment of*
13 *such incidental nonmedical expenses that are so in-*
14 *curring as the Secretary determines by regulation to be*
15 *appropriate.*

16 *“(b) ELIGIBILITY.—*

17 *“(1) IN GENERAL.—Payments under subsection*
18 *(a) may be made for the qualifying expenses of a do-*
19 *nating individual only if—*

20 *“(A) the State in which the donating indi-*
21 *vidual resides is a different State than the State*
22 *in which the intended recipient of the organ re-*
23 *sides; and*

24 *“(B) the annual income of the intended re-*
25 *ipient of the organ does not exceed \$35,000 (as*

1 *adjusted for fiscal year 2001 and subsequent fis-*
2 *cal years to offset the effects of inflation occur-*
3 *ring after the beginning of fiscal year 2000).*

4 “(2) *CERTAIN CIRCUMSTANCES.*—*Subject to*
5 *paragraph (1), the Secretary may in carrying out*
6 *subsection (a) provide as follows:*

7 “(A) *The Secretary may consider the term*
8 *‘donating individuals’ as including individuals*
9 *who in good faith incur qualifying expenses to-*
10 *ward the intended donation of an organ but with*
11 *respect to whom, for such reasons as the Sec-*
12 *retary determines to be appropriate, no donation*
13 *of the organ occurs.*

14 “(B) *The Secretary may consider the term*
15 *‘qualifying expenses’ as including the expenses of*
16 *having one or more family members of donating*
17 *individuals accompany the donating individuals*
18 *for purposes of subsection (a) (subject to making*
19 *payment for only such types of expenses as are*
20 *paid for donating individuals).*

21 “(c) *LIMITATION ON AMOUNT OF PAYMENT.*—

22 “(1) *IN GENERAL.*—*With respect to the geo-*
23 *graphic area to which a donating individual travels*
24 *for purposes of subsection (a), if such area is other*
25 *than the covered vicinity for the intended recipient of*

1 *the organ, the amount of qualifying expenses for*
2 *which payments under such subsection are made may*
3 *not exceed the amount of such expenses for which pay-*
4 *ment would have been made if such area had been the*
5 *covered vicinity for the intended recipient, taking into*
6 *account the costs of travel and regional differences in*
7 *the costs of living.*

8 “(2) *COVERED VICINITY.*—*For purposes of this*
9 *section, the term ‘covered vicinity’, with respect to an*
10 *intended recipient of an organ from a donating indi-*
11 *vidual, means the vicinity of the nearest transplant*
12 *center to the residence of the intended recipient that*
13 *regularly performs transplants of that type of organ.*

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

21 “(1) *under any State compensation program,*
22 *under an insurance policy, or under any Federal or*
23 *State health benefits program; or*

24 “(2) *by an entity that provides health services on*
25 *a prepaid basis.*

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

2 “(1) *The term ‘covered vicinity’ has the meaning*
3 *given such term in subsection (c)(2).*

4 “(2) *The term ‘donating individuals’ has the*
5 *meaning indicated for such term in subsection (a)(1),*
6 *subject to subsection (b)(2)(A).*

7 “(3) *The term ‘qualifying expenses’ means the*
8 *expenses authorized for purposes of subsection (a),*
9 *subject to subsection (b)(2)(B).*

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

14 **SEC. 6. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.**
15 **TIONS.**

16 *Part H of title III of the Public Health Service Act,*
17 *as amended by section 5 of this Act, is amended by inserting*
18 *after section 376 the following section:*

19 “*PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS*

20 “*SEC. 377. (a) PUBLIC AWARENESS.*—*The Secretary*
21 *shall (directly or through grants or contracts) carry out a*
22 *program to educate the public with respect to organ dona-*
23 *tion, including the need to provide for an adequate rate of*
24 *such donations.*

25 “(b) *STUDIES AND DEMONSTRATIONS.*—*The Secretary*
26 *may make grants to public and nonprofit private entities*

1 *for the purpose of carrying out studies and demonstration*
2 *projects with respect to providing for an adequate rate of*
3 *organ donation.*

4 “(c) *ANNUAL REPORT TO CONGRESS.—The Secretary*
5 *shall annually submit to the Congress a report on the ac-*
6 *tivities carried out under this section, including provisions*
7 *describing the extent to which the activities have affected*
8 *the rate of organ donation.*

9 “(d) *AUTHORIZATION OF APPROPRIATIONS.—*

10 “(1) *IN GENERAL.—For the purpose of carrying*
11 *out this section, there are authorized to be appro-*
12 *priated \$10,000,000 for fiscal year 2000, and such*
13 *sums as may be necessary for each of the fiscal years*
14 *2001 through 2005. Such authorization of appropria-*
15 *tions is in addition to any other authorizations of ap-*
16 *propriations that is available for such purpose.*

17 “(2) *STUDIES AND DEMONSTRATIONS.—Of the*
18 *amounts appropriated under paragraph (1) for a fis-*
19 *cal year, the Secretary may not obligate more than*
20 *\$2,000,000 for carrying out subsection (b).”.*

21 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

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

1 “AUTHORIZATION OF APPROPRIATIONS FOR ORGAN
2 PROCUREMENT AND TRANSPLANTATION NETWORK

3 “SEC. 378. (a) OPERATION OF NETWORK.—For the
4 purpose of providing for the Organ Procurement and
5 Transplantation Network under section 372, including the
6 scientific registry, there are authorized to be appropriated
7 \$6,000,000 for fiscal year 2000, and such sums as may be
8 necessary for each of the fiscal years 2001 through 2005.

9 “(b) INCREASING ORGAN DONATION AND PROCURE-
10 MENT.—For the purpose of increasing organ donation and
11 procurement through the Organ Procurement and Trans-
12 plantation Network under section 372, there are authorized
13 to be appropriated such sums as may be necessary for each
14 of the fiscal years 2000 through 2005. Such authorization
15 of appropriations is with respect to such purpose in addi-
16 tion to the authorization of appropriations established in
17 subsection (a).”.

18 **SEC. 8. EFFECTIVE DATE.**

19 *The amendments made by this Act take effect October*
20 *1, 1999, or upon the date of the enactment of this Act,*
21 *whichever occurs later.*