106TH CONGRESS, 1st Session | HOUSE OF REPRESENTATIVES | REPORT 106–429

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK AMENDMENTS OF 1999

NOVEMBER 1, 1999.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 2418]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 2418) to amend the Public Health Service Act to revise and extend programs relating to organ procurement and transplantation, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Organ Procurement and Transplantation Network Amendments of 1999".

SEC. 2. FINDINGS.

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

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

(2) The Organ Procurement and Transplantation Network ("Network"), which was established in the private sector pursuant to a contract awarded by the Federal Government, should continue to be operated by a nonprofit private entity pursuant to a contract with the Federal Government.

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

(4) The responsibility for developing, establishing, and maintaining medical criteria and standards for organ procurement and transplantation belongs in the private sector and is a function of the Network.

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

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

(b) SENSE OF CONGRESS REGARDING FAMILY DISCUSSIONS OF ORGAN DONATIONS.—The Congress recognizes the importance of families pledging to each other to share their lives as organ and tissue donors and acknowledges the importance of discussing organ and tissue donation as a family.

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

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

(2) acknowledges the advances in medical technology that have enabled organ transplantation with organs donated by living individuals to become a viable treatment option for an increasing number of patients.

SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

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

"ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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

"(1) The Network shall be an independent, nonprofit private entity that is a separate legal entity from the entity to which such contract is awarded.

"(2) The Network shall in accordance with criteria under subsection (b)(3) include as members qualified organ procurement organizations (as described in section 371(b)), transplant centers, and other entities that have a demonstrated interest in the fields of organ donation or transplantation. (Such members are in this section referred to as 'Network participants'.)

"(3) The Network shall have a board of directors (in this section referred to as the 'Board'). The Board shall, after consultation with Network participants, establish the policies for carrying out the functions described in this section for the Network.

"(4) The Board shall be in accordance with the following:

"(A) The Board shall include representatives of qualified organ procurement organizations, transplant centers, voluntary health associations, and the general public, including a reasonable proportion of the members of the Board who are patients awaiting a transplant or transplant recipients or individuals who have donated an organ or family members of patients, recipients or donors.

"(B) The Board shall establish membership categories and qualifications with respect to serving on the Board, and shall have exclusive authority to admit individuals to membership on the Board. Transplant surgeons and transplant physicians shall comprise not less than 50 percent of the membership of the Board. The Board shall be limited to a total of 42 members.

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

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

"(b) GENERAL FUNCTIONS.—The following applies to the Network:

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

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

"(3) The Network shall establish criteria for being a Network participant, shall establish medical criteria for listing patients and for allocating organs, and shall provide to members of the public an opportunity to comment with respect to such criteria.

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

"(5) The Network shall assist organ procurement organizations in the distribution of organs. The distribution of organs shall be based on medical criteria established by the Network, and also shall be based on equity and ethics without regard to economic status of those awaiting organ transplants and without political control or influence.

"(6) The Network shall adopt and use standards of quality for the acquisition and transportation of donated organs, including standards regarding the transmission of infectious diseases.

"(7) The Network shall prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors.

"(8) The Network shall coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers.

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

"(10) The Network shall establish criteria, policies, and procedures to address the disparity in mortality rates between children and adults while waiting for organ transplants.

"(c) SCIENTIFIC REGISTRY.—

"(1) IN GENERAL.—The Network shall maintain a scientific registry of patients awaiting organ transplantation, persons from whom organs are removed for transplantation, and organ transplant recipients for the ongoing evaluation of the scientific and clinical status of organ transplantation.

"(2) REPORTS.—The Network shall prepare for inclusion in the report under section 375 an analysis of scientifically and clinically valid information derived from the scientific registry under paragraph (1).

"(d) INFORMATION AND DATA.—

"(1) IN GENERAL.—The Network shall—

"(A) provide information to physicians and other health professionals regarding organ donation and transplantation; and

"(B) collect, analyze, and annually publish data concerning organ donation and transplantation.

"(2) INFORMATION FOR PATIENTS AND GENERAL PUBLIC.—The Network shall make available to patients in need of organ transplants information in accordance with the following:

"(A) The information shall be transplant-related information specific to transplant centers that are Network participants, which information has been determined by the Network to be scientifically and clinically valid.

"(B) The information shall be designed to assist patients and referring physicians in choosing a transplant center, including information on the supply of and demand for organs.

"(C) With respect to the patient involved, the information shall (taking into account patients in similar medical circumstances) include the following as applied to specific transplant centers:

"(i) The probability of receiving an organ transplant.

"(ii) The length of time that similarly situated patients have waited historically to receive a transplant.

"(iii) Medical outcomes for similarly situated patients, which information shall be adjusted to reflect the medical risk factors for such patients.

"(D) With respect to the patient involved, the information shall include the information described in subparagraph (C) as applied to the service areas of specific qualified organ procurement organizations (other than such areas in which there is only one transplant center).

"(E) Information under this paragraph shall be updated not less frequently than once a year.

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

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

"(A) Information that permits direct or indirect identification of any patient who is waiting for a transplant, or who is an organ transplant patient or recipient of an organ.

"(B) Information that permits direct or indirect identification of any potential or actual organ donors.

"(C) Information that permits direct or indirect identification of participants in Network deliberations or determinations related to practitioner or institutional qualifications, due process proceedings or peer review activities, except for information announcing final decisions of the Network.

This paragraph may not be construed as prohibiting the disclosure of information within the Network, including information disclosed in the course of interactive organ sharing operations within the Network.

"(e) STUDIES.—

"(1) IN GENERAL.—The Network shall carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs or limited access to transplantation, and among children.

"(2) CERTAIN TECHNOLOGIES.—The Network may study the impact of possible transplantation of animal organs (xenotransplantation) and other technologies to determine the impact upon, and prevent negative effects on, the fair and effective use of human allograft organs.

"(f) QUALITY ASSURANCE; MONITORING OF NETWORK PARTICIPANTS.—The Network shall monitor the operations of Network participants to the extent appropriate for determining whether the participants are maintaining compliance with criteria under subsection (b)(3). In monitoring a Network participant under the preceding sentence, the Network shall inform the participant of any findings indicating noncompliance by the participant.

"(g) QUALITY ASSURANCE; PEER REVIEW PROCEEDINGS.—

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

"(2) NONCOMPLIANCE.—

"(A) PAYMENT OF DAMAGES.—The Network shall require that, as a condition of being a Network participant, each such participant agree that the Network may, through a peer review proceeding under paragraph (1), require the participant to pay damages for the failure of the participant to comply with criteria under subsection (b)(3). The Network shall establish procedures to ensure that such proceedings are conducted in an impartial manner, with adequate opportunity for the Network participant involved to receive a hearing. The Network shall identify various types of violations of

such criteria and specify the maximum amount of damages that the Network may under this subparagraph require a Network participant to pay for the type of violation involved.

"(B) RESTRICTING ACCESS TO ALLOCATION SYSTEM.—If under subparagraph (A) it has been determined that a Network participant has engaged in substantial violations of criteria under subsection (b)(3), the Network may restrict the extent to which such participant is permitted to receive allocations of organs through the Network.

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

"(3) CONFIDENTIALITY.—With respect to a peer review proceeding under paragraph (1), neither the Network nor the Secretary has authority to release data or information to the public relating to the proceedings without the written permission of all the parties involved, except that if damages under paragraph (2) are required to be paid, the requirement may be publicly announced after the conclusion of the proceeding.

"(h) ADMINISTRATIVE PROVISIONS.—

"(1) LIMITATION ON AMOUNT OF CONTRACT.—The amount provided under a contract under subsection (a) in any fiscal year may not exceed $6,000,000 for the operation of the Network, including the scientific registry under subsection (c). Such limitation does not apply to amounts provided under the contract for increasing organ donation and procurement.

"(2) RELATIONSHIP BETWEEN SECRETARY AND NETWORK.—The administrative and procedural functions described in this section for the Network shall be carried out in accordance with the mutual agreement of the Secretary and the Network. For purposes of the preceding sentence, functions that are scientific, clinical, or medical in nature are not administrative or procedural functions and are within the sole discretion of the Network. With respect to the programs under titles XVIII and XIX of the Social Security Act, this section may not be construed as having any legal effect on such programs, except to the extent that section 1138 of such Act, or any other provision of such Act, provides otherwise.

"(3) NONFEDERAL ASSETS OF NETWORK.—

"(A) IN GENERAL.—No assets in the possession of the Network or revenues collected by the Network, other than amounts appropriated under section 378, shall be considered or be treated as Federal property, Federal revenues, or program funds pursuant to a Federal contract, nor shall such assets, revenues, or nonappropriated funds be subject to restriction or control by the Secretary, nor shall any member of the Network be required by the Secretary to pay any fees to the Network, nor shall the Secretary be authorized to collect or authorize collection of service fees with respect to the Network or the scientific registry under subsection (c).

"(B) GIFTS.—This section does not prohibit the Network from accepting gifts of money or services, including gifts to carry out activities to provide for an increase in the rate of organ donation.

"(4) COMMUNITY ENDORSEMENT OF CONTRACT RECIPIENT.—In the case of any contract under subsection (a) that is awarded after the date of the enactment of the Organ Procurement and Transplantation Network Amendments of 1999, the Secretary shall select an applicant to receive the contract from among applicants that have the written endorsement of a majority of the combined total number of transplant centers and qualified organ procurement organizations that are Network participants (without regard to whether such centers or organizations endorse more than one applicant for the contract).

"(5) CHANGE IN CONTRACT RECIPIENT.—With respect to the expiration of the period during which a contract under subsection (a) is in effect, if the Secretary makes a determination to award the contract to a different entity than the entity to which the previous contract under such subsection was awarded, the Secretary shall publish in the Federal Register a notice that such change in the administration of the Network will take place, and the change may not take effect any sooner than the expiration of the six-month period beginning on the date on which the notice is so published. Such a change does not affect the membership status of any Network participant, or the membership status of any individual who serves on the Board (other than any membership position that is predicated solely on being a representative of the current contractor under subsection (a)).

"(i) ADDITIONAL PROCEDURES REGARDING OVERSIGHT AND PUBLIC ACCOUNTABILITY.—For purposes of providing oversight of and public accountability for the operation of the Network, the Secretary shall establish procedures for—

"(1) conducting public hearings and receiving from interested persons comments regarding criteria of the Network and critical comments relating to the manner in which the Network is carrying out its duties under this section;

"(2) providing such comments to the Network and receiving responses from the Network; and

"(3) the consideration by the Secretary of such comments.

"(j) EVALUATIONS BY GENERAL ACCOUNTING OFFICE.—

"(1) IN GENERAL.—The Comptroller General of the United States shall periodically conduct evaluations of the Network, including the structure and function of the Network and the relationship between the Secretary and the nonprofit private entity that under subsection (a) operates the Network. The first such evaluation shall be completed not later than one year after the date of the enactment of the Organ Procurement and Transplantation Network Amendments of 1999, and such an evaluation shall be completed not later than every second year thereafter.

"(2) INPUT FROM FIELD.—In conducting evaluations under paragraph (1), the Comptroller General shall consult with organizations that represent transplant surgeons, transplant physicians, transplant centers, and qualified organ procurement organizations, and with other experts in the field of organ transplantation, including experts who are not members of the Board of the Network or of the executive structure of the contractor under subsection (a) .

"(3) PROCEDURES OF NETWORK.—The Network shall establish procedures for coordinating with the Comptroller General for purposes of evaluations under paragraph (1).

"(4) REPORTS TO CONGRESS.—

"(A) COMPTROLLER GENERAL.—The Comptroller General shall prepare reports describing the findings of evaluations under paragraph (1) and shall submit such reports to the Committee on Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate. The Comptroller General shall provide a copy of each such report to the Network.

"(B) NETWORK.—Not later than 180 days after the date on which a report is submitted under subparagraph (A), the Network shall submit to each of the committees specified in such subparagraph a report describing any actions the Network has taken in response to the report under subparagraph (A).".

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

SEC. 4. ADDITIONAL AMENDMENTS.

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

(1) by striking section 373;

(2) in section 374—

(A) in subsection (b)(1), by inserting after "organization" the following: "and other organizations for the purpose of increasing the supply of transplantable organs";

(B) in subsection (c), by striking "or 373" each place such term appears; and

(C) in subsection (d), by amending paragraph (2) to read as follows:

"(2) The term 'organ', with respect to transplantation into humans, means the human or other animal kidney, liver, heart, lung, pancreas, and any other organ (other than human corneas and eyes) specified by the Secretary by regulation. For purposes of section 372(c), such term includes bone marrow.";

(3) in section 375—

(A) in paragraph (1), by striking "this part" and inserting "this section"; and

(B) in paragraph (4)—

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

(ii) in subparagraph (B) (as so redesignated), by striking "comparative costs and patient outcomes" and inserting "comparative patient outcomes";

(4) in section 376—

(A) by striking "the Secretary" and inserting "the Organ Procurement and Transplantation Network under section 372"; and

(B) by striking "Committee on Energy and Commerce" and inserting "Committee on Commerce"; and

(5) by striking section 377.

(b) REDESIGNATIONS.—Part H of title III of the Public Health Service Act, as amended by subsection (a) of this section, is amended by redesignating sections 374 through 376 as sections 373 through 375, respectively.

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

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

(2) by moving subparagraph (F) (as so redesignated) two ems to the left; and

(3) by inserting after subparagraph (C) the following:

"(D) notwithstanding any other provision of law, has met the other requirements of this subsection and has been certified or recertified by the Secretary as meeting the performance standards to be a qualified organ procurement organization through a process which—

"(i) granted certification or recertification within the previous 4 years with such certification in effect as of October 1, 1999, and remaining in effect through the earlier of—

"(I) January 1, 2002, or

"(II) the completion of recertification under the requirements of clause (ii); or

"(ii) is defined through regulations promulgated by the Secretary not later than January 1, 2002, which—

"(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

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

"(III) provide for the filing and approval of a corrective action plan by a qualified organ procurement organization that fails to meet the performance standards and a grace period of not less than 3 years during which such organization can implement the corrective action plan without risk of decertification; and

"(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds;".

SEC. 5. PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION.

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

"PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION

"SEC. 376. (a) IN GENERAL.—The Secretary may make awards of grants or contracts to States, transplant centers, qualified organ procurement organizations under section 371, or other public or private entities for the purpose of—

"(1) providing for the payment of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred as 'donating individuals'); and

"(2) in addition, providing for the payment of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

"(b) ELIGIBILITY.—

"(1) IN GENERAL.—Payments under subsection (a) may be made for the qualifying expenses of a donating individual only if—

"(A) the State in which the donating individual resides is a different State than the State in which the intended recipient of the organ resides; and

"(B) the annual income of the intended recipient of the organ does not exceed $35,000 (as adjusted for fiscal year 2001 and subsequent fiscal years to offset the effects of inflation occurring after the beginning of fiscal year 2000).

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

"(A) The Secretary may consider the term 'donating individuals' as including individuals who in good faith incur qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs.

"(B) The Secretary may consider the term 'qualifying expenses' as including the expenses of having one or more family members of donating individuals accompany the donating individuals for purposes of subsection (a) (subject to making payment for only such types of expenses as are paid for donating individuals).

"(c) LIMITATION ON AMOUNT OF PAYMENT.—

"(1) IN GENERAL.—With respect to the geographic area to which a donating individual travels for purposes of subsection (a), if such area is other than the covered vicinity for the intended recipient of the organ, the amount of qualifying expenses for which payments under such subsection are made may not exceed the amount of such expenses for which payment would have been made if such area had been the covered vicinity for the intended recipient, taking into account the costs of travel and regional differences in the costs of living.

"(2) COVERED VICINITY.—For purposes of this section, the term 'covered vicinity', with respect to an intended recipient of an organ from a donating individual, means the vicinity of the nearest transplant center to the residence of the intended recipient that regularly performs transplants of that type of organ.

"(d) RELATIONSHIP TO PAYMENTS UNDER OTHER PROGRAMS.—An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

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

"(2) by an entity that provides health services on a prepaid basis.

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

"(1) The term 'covered vicinity' has the meaning given such term in subsection (c)(2).

"(2) The term 'donating individuals' has the meaning indicated for such term in subsection (a)(1), subject to subsection (b)(2)(A).

"(3) The term 'qualifying expenses' means the expenses authorized for purposes of subsection (a), subject to subsection (b)(2)(B).

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

SEC. 6. PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS.

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

"PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS

"SEC. 377. (a) PUBLIC AWARENESS.—The Secretary shall (directly or through grants or contracts) carry out a program to educate the public with respect to organ donation, including the need to provide for an adequate rate of such donations.

"(b) STUDIES AND DEMONSTRATIONS.—The Secretary may make grants to public and nonprofit private entities for the purpose of carrying out studies and demonstration projects with respect to providing for an adequate rate of organ donation.

"(c) ANNUAL REPORT TO CONGRESS.—The Secretary shall annually submit to the Congress a report on the activities carried out under this section, including provisions describing the extent to which the activities have affected the rate of organ donation.

"(d) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2005. Such authorization of appropriations is in addition to any other authorizations of appropriations that is available for such purpose.

"(2) STUDIES AND DEMONSTRATIONS.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may not obligate more than $2,000,000 for carrying out subsection (b).".

SEC. 7. AUTHORIZATION OF APPROPRIATIONS.

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

"AUTHORIZATION OF APPROPRIATIONS FOR ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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

"(b) INCREASING ORGAN DONATION AND PROCUREMENT.—For the purpose of increasing organ donation and procurement through the Organ Procurement and Transplantation Network under section 372, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2000 through 2005. Such authorization of appropriations is with respect to such purpose in addition to the authorization of appropriations established in subsection (a).".

SEC. 8. EFFECTIVE DATE.

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

PURPOSE AND SUMMARY

H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999, ensures that decision making with regard to organ transplantation remains, as originally intended under the National Organ Transplant Act of 1984 (NOTA) (Public Law 98–507), in the transplant community.

The bill also requires that new, timely, and transplant center-specific information be made available to the public. The bill provides statutory requirements for the dissemination of this material to avoid reliance upon administrative mechanisms, as is currently the case.

H.R. 2418 also creates new incentives for people to become organ donors and provides for studies to discover who has the most innovative and successful approaches to organ recovery and donation around the country.

BACKGROUND AND NEED FOR LEGISLATION

Solid organ transplantation is perhaps the most uniquely complex medical and surgical procedure performed in the modern era of medicine. It is unique in that transplantation depends entirely on the supply of donor organs, which is a product of the generosity of the American people. However, that supply continues to be tragically short of the need for transplantation among patients with end-stage organ disease and organ failure. Every year the number of patients who die while waiting for a transplant increases, as does the national waiting list, which now exceeds 65,000 patients waiting for kidney, liver, heart, lung, pancreas, and intestine transplants.

For these compelling reasons, and to insulate organ transplantation from political control or interference, Congress established a structure in the private sector to encourage and facilitate the effort of organ procurement and transplantation throughout the country. In doing so, Congress has consistently recognized that the management and formulation of policies applicable to this field of medicine is best left in the expert hands of the medical community, the pa-

tients, and donor families who are most directly affected. The role of the Federal government in this network has been carefully restricted by statute to providing technical assistance to the private sector together with appropriate oversight of Federal funding.

On April 2, 1998, the Secretary of Health and Human Services (the Secretary) issued a Final Rule regarding implementation of the NOTA (42 U.S.C. 274), which contained provisions that ran counter to fifteen years of Congressional legislation relating to NOTA. The April 2, 1998, Final Rule drew immediate and widespread criticism throughout the transplant community of transplant surgeons and physicians, affiliated healthcare professionals, patients, donors and their families, and State and local governments. H.R. 2418 responds to Secretarial claims made in the regulation, amends and restates provisions of the NOTA to clarify and reaffirm the Act's existing provisions, and where necessary, adds new provisions to address concerns raised in Committee hearings.

History of the organ procurement and transplantation network, scientific registry, and organ allocation

Establishment of the Organ Procurement and Transplantation Network. In an effort to assist transplant centers to facilitate the sharing of organs through a clearinghouse of similar institutions, the National Organ Transplant Act of 1984 directed the Secretary of the Department of Health and Human Services (HHS or the Department) to establish by contract the Organ Procurement and Transplantation Network (OPTN or the Network), which would establish the policies to govern allocation of organs throughout the country. NOTA also established the Task Force on Organ Transplantation for the purpose of conducting a comprehensive study on medical, social, economic, and ethical issues related to organ transplantation. The Task Force on Organ Transplantation published a report in 1986 (Organ Transplantation: Issues and Recommendations) offering recommendations including a call for the establishment of a national system or network for matching organ donors with organ transplant recipients. The Task Force recommended, among other things, that members of the OPTN adopt uniform policies for the OPTN and improve efforts in public education to increase organ donation. On September 30, 1986, HHS awarded the contract to establish and run the OPTN to the United Network for Organ Sharing (UNOS), a private, nonprofit corporation.

One recommendation the Task Force made to Congress in 1986 is that information be published annually to inform the public of the status of organ transplant activity at each transplant center. Subsequently, section 373 of NOTA established the Scientific Registry. The purpose of the Scientific Registry is to maintain information on patients and transplants and transplant procedures for assessing the scientific and clinical status of organ transplantation. Currently, the Scientific Registry maintains a data request system and produces an annual statistical report for the public and a report on patient survival rates. UNOS also competed for and won the contract from HHS to operate the Scientific Registry.

Perhaps the most important provision of NOTA was the establishment of the principle that the Network would be a private sector entity, and that the Federal government would encourage and

assist by providing contract funding. NOTA was very specific in this regard. It stated that "[T]he Secretary shall *by contract provide for* the establishment and operation of an organ procurement and transplantation network * * *" (42 U.S.C. 274; emphasis added). Indeed, the accompanying legislative history made it clear that the Secretary was not authorized to establish and operate the Network within the government. The report reinforced NOTA's basic premise that the role of the Secretary was that of providing funding by contract for the establishment and operation of the Network in the private sector. In the report, the Senate Committee on Labor and Human Resources found:

> * * * sufficient cause to believe that the national coordinating effort, while stimulated by the federal government and this legislation, should nonetheless be located in the private sector rather than in government. In this regard, the Committee is aware and encourages the very worthwhile effort, established in the private sector with the assistance of the Federal Government through the office of the Surgeon General of the United States, to provide a cohesive and united policy for organ transplantation. (Senate Report No. 98–382, Apr. 6, 1984)

NOTA provided that the Network was to be a private nonprofit entity with a board of directors which includes representatives of organ procurement organizations, transplant centers, voluntary health associations, and the general public. NOTA also described the duties to be performed by the Network in achieving its mission of enhancing the effectiveness and efficiency of the national organ procurement and transplantation effort. These duties included the creation of a national list of patients waiting for a transplant and a national system using computers to match donated organs with patients on the list in accordance with established medical criteria. The Network was to have a 24-hour telephone service to facilitate matching, help Organ Procurement Organizations (OPOs) distribute organs that could not be placed within the OPOs' service areas, and assist in coordinating the transportation of organs from OPOs to transplant centers. The Network was also given the responsibility for collecting, analyzing, and publishing data concerning organ donation and transplantation and for providing information to physicians and other health professionals regarding organ donation.

Federal Oversight and Authority. By defining the relationship between the Secretary and the Network as contractual in nature, the Congress established a mechanism that gave the Federal government effective oversight of the expenditure of appropriated funds through the enormous body of Federal contract law and regulation. This approach ensured that the Network only conducted those activities authorized by law and agreed to by the Secretary under contract. The Network is therefore fully accountable to the Secretary and the public through this oversight mechanism, and the Secretary has the power to prevent implementation by the Network of anything deemed to be harmful to the public.

NOTA also required that the Secretary designate and maintain a unit in the Public Health Service to administer part H of the

Public Health Service Act, dealing with organ allocation, and to provide assistance to organ procurement organizations, the Organ Procurement and Transplant Network, and the Scientific Registry, and provide technical assistance to organ procurement organizations receiving grants and contracts for organ transplant activities. In addition, current law requires the Secretary to conduct public education programs that (1) aim to increase the donation of organs; (2) provide information to patients, their families, and their physicians; and (3) provide technical assistance to the OPTN, organ procurement organizations, and others involved in the donation, procurement, and transplantation of organs. The Secretary is given no authority to supplant the policymaking role of the OPTN.

NOTA did not authorize the Secretary to establish medical criteria or policies for the Network. Such authority was expressly left to the private sector. Nor did NOTA authorize the Secretary to impose fees, require payments from those obtaining Network services, exercise control over private funds or assets obtained by the Network or the Network contractor, or regulate the field of organ transplantation beyond any authority established otherwise under law.

Since 1986, UNOS has competed for and been awarded the contract to operate the OPTN. Current law requires that the OPTN have a board of directors that includes representatives of organ procurement organizations, transplant centers, voluntary health associations, and the general public. The board of directors for the OPTN comprises 38 members who represent the perspectives of physicians, surgeons, patients, patient advocates, organ procurement organizations, organ donors, transplant recipients and their families, patient advocates, histocompatibility (tissue-typing) laboratories, transplant coordinators, bioethicists, the general public, and others. A total of 434 transplant-related organizations (such as transplant hospitals, laboratories, and organ procurement organizations) comprise the membership of the OPTN.

In 1986, Section 1138 of the Social Security Act was amended (Omnibus Budget Reconciliation Act of 1986, Public Law 99–509) to require that transplant centers and organ procurement organizations who are members of the OPTN abide by the rules and policies of the OPTN. That requirement became a condition of participation in the Federally supported Medicare and Medicaid programs. In 1994, Congress further amended section 1138 of the Social Security Act (Social Security Act Amendments of 1994, Public Law 103–432) to require that transplant hospitals establish written agreements with organ procurement organizations for the purpose of identifying potential organ donors in designated service areas.

1986 Omnibus Budget Reconciliation Act. In the 1986 Omnibus Budget Reconciliation Act (1986 OBRA), Congress amended the Social Security Act by adding a new provision to section 1138, which required that:

> The Secretary shall provide that a hospital meeting the requirements of title XVIII or XIX may participate in the program established under such title only if * * * in the case of a hospital in which organ transplants are performed, the hospital is a member of, and abides by the

> rules and requirements of, the Organ Procurement and Transplantation Network * * *
>
> The Secretary shall provide that payment may be made under title XVIII or XIX with respect to organ procurement costs attributable to payments made to an organ procurement agency only if the agency * * * is a member of, and abides by the rules and requirements of, the Network; allocates organs, within its service area and nationally, in accordance with medical criteria and the policies of the Network.

Nothing in this OBRA provision was intended to change the basic nature of the Network or the relationship between the Federal government and the Network as specified in the Transplant Act. However, due to this new condition for participation in Medicare and Medicaid, concerns were expressed about the propriety of a Federal law requiring membership in a private organization and adherence to such organization's rules and requirements. Therefore, Congress made several changes to the National Organ Transplant Act in 1988 to address such concerns.

1988 Transplant Act Amendments. The 1988 amendments did not alter the original concept of a private sector Network but added requirements for the Network's adoption of membership criteria and policies. The approach prescribed by those amendments substantively addressed the same issues as the Administrative Procedures Act (APA) for the adoption of Federal rules, which includes giving the public notification of, and an opportunity to comment on, proposed policies. The 1988 amendments required the private sector Network to formally adopt and publish its membership criteria and the medical criteria for organ allocation and to provide members of the public the opportunity to comment on them.

The 1988 amendments enhanced the Secretary's oversight role by requiring that the Secretary "establish procedures for receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network * * * and the consideration by the Secretary of such comments."

In addressing the provisions in the 1986 OBRA, the 1988 amendments of NOTA ensured that there was adequate governmental oversight of the Network to avoid any problems regarding improper delegation of authority. The Network was given only the power to establish such criteria as are permitted under the Secretary's contract, and the Secretary has the authority to ensure that the Network cannot act without Federal oversight. By addressing the substantive public policy issues that the APA seeks to address, and by giving the Secretary authority to seek public comments as well, the 1988 amendments adequately addressed these concerns.

NOTA was amended in 1988 and 1990 to modify requirements in the roles for and functions of the OPTN and, among other things, requirements for the OPTN to assist in organ allocation. In 1988, Congress enacted the Health Programs Extension of 1988 (Public Law 100–607) to (1) establish a grant program for organ procurement organizations and encourage the increased donation of organs, (2) require that organ procurement organizations and hospitals cooperate in establishing and implementing routine referral

and inquiry protocols for organ donations, (3) require the Secretary to establish procedures for receiving and considering comments critical of the OPTN, and (4) require the Secretary to work with the OPTN to resolve issues about the OPTN.

The Transplant Amendments Act of 1990 (Public Law 101–616) made significant revisions in the operation and management of the OPTN, and placed public policy restraints on the OPTN board to guide its actions. The law (1) required that organs be distributed equitably among patients; (2) modified requirements in the OPTN's board of directors; (3) required the Secretary to establish performance standards to increase the effectiveness and efficiency of organ procurement organizations in the procurement and equitable distribution of organs; and (4) required that transplant center-specific information about survival rates, outcomes, and costs be made available to the public.

Policy issues and reauthorization of the OPTN

Organ Allocation. The allocation process for organs is predicated on scientific and medical judgment. One premise for the successful transplantation of organs is the relative genetic or medical histocompatibility shared by the organ donor and recipient. This compatibility, which is expressed in the unique characteristics or qualities of the tissue that makes up the organ, is assessed by using a series of tests for establishing a medical match. Organ procurement organizations and transplant hospitals evaluate tissue matching along with other medical criteria in their decisions to allocate an organ consistent with OPTN policies.

Medical criteria constitute a critical first step in the distribution of organs. The medical criteria seek to optimize the level of biologic and genetic similarities shared by a donor and host to minimize the possibility of graft rejection. The greater the medical compatibility, the greater the chances for a successful transplant operation and long-term survival. The medical criteria establish the scientific basis for matching organs. Other criteria include the likelihood of graft and host survival, medical status, and length of time spent in the intensive care unit. However, it should be noted that for each organ, the OPTN has articulated an organ allocation policy that permits transplant centers to consider different criteria for transplantation such as a patient's age, the availability of alternative therapies, or history of repeat transplantation.

Relationship of the Secretary to the OPTN. The Secretary has an administrative and oversight function in the activities of the OPTN, and the Secretary articulated that role in the April 2, 1998, final rule (63 Fed. Reg. 16296 (1998)). However, the Secretary's interpretation of the extent to which the Secretary should be involved in OPTN policy-making was a source of considerable debate throughout 1998 and 1999. Physicians, transplant surgeons, and some patient advocacy groups testified before the House Committee on Commerce on June 18, 1998, in favor of Congressional clarification of the role of the Secretary as the administrator of the OPTN with oversight responsibilities, but without any direct role in the scientific, medical, or policy-making activities of the OPTN (Serial No. 105–107).

Role of Organ Procurement Organizations. The Committee recognizes the need to increase organ donation within the United States, and the important role of OPOs in that effort. The current process for certification and recertification of OPOs has created a level of uncertainty that is interfering with OPO effectiveness in raising the level of donation. The General Accounting Office (GAO), the Institute of Medicine (IOM), and a number of private organizations have identified substantial limitations of the current OPO certification and recertification process conducted by HHS. These limitations include the use of current population-based performance measures to certify OPOs that do not result in improved performance and accountability for OPOs. The process has been criticized also for decertifying OPOs solely on the basis of these measures without the opportunity for corrective action or due process.

In the Balanced Budget Act of 1997 (Public Law 105–33), Congress intended to reduce the uncertainty of OPO recertification by granting authority to the Department of Health and Human Services to extend the period for recertification of all OPOs from two (2) to four (4) years. The Committee intends that the Department will now extend the recertification period for all OPOs to four years, and will use this extended period to substantially revise the process and criteria for certification to solve the problems that have been identified with the process. The Committee does not intend that the Department will reverse or alter any certification or recertification decision made by the Department prior to the date this provision was approved by the Committee. The Committee also does not intend to prevent the Department from decertifying in the future an OPO for failure to meet any of the OPOs standards created by this section or any other applicable statute other than the performance standards addressed in this subsection.

The Committee intends that the Department will work collaboratively with the organ procurement community in the effort to revise the current OPO certification and recertification process. The Department will collaborate on a review of alternative approaches to performance measurement, including those suggested by the GAO, the IOM, and the Harvard School of Public Health, and will design new performance measures that would take into account process variables and donor potential within an OPO service area. The Committee intends that the Department will revise the certification process to reduce the uncertainty and randomness of the current process by providing OPOs with appropriate safeguards such as an appropriate grace period to file corrective action plans and other due process rights. The Committee intends that currently certified OPOs will continue to meet the requirements of this subsection until the alternative performance standards described in this subsection have been promulgated by the Department and the performance of each of the OPOs has been reviewed in relation to these alternative standards.

Does the Sick Chicken Case Still Rule the Roost? At the Full Committee markup, the Committee also considered whether *Schechter Poultry Corp.* v. *United States* (295 U.S. 495 (1935)) still serves as a barricade to Congressional delegation of policy-making authority to private-sector entities like the Organ Procurement and Transplantation Network. The *Schechter* case, along with *Carter* v.

Carter Coal Co., 298 U.S. 238 (1936), proved to be the last constitutional barrier to the implementation of the New Deal over the question of the delegation doctrine.

While the Supreme Court has continued to state that congressional delegations to private parties are disfavored, the High Court has not, in fact, struck down any such enactments in the ensuing years. As Justice Marshall wrote, "The notion that the Constitution narrowly confines the power of Congress to delegate authority to administrative agencies, which was briefly in vogue in the 1930's, has been virtually abandoned by the Court for all practical purposes * * *." *FPC* v. *New England Power Co.,* 415 U.S. 345, 352–3 (1974) (Marshall, J., concurring and dissenting). This reticence has occurred in the face of numerous instances in which Congress has specifically included private parties in the implementation of Federal legislation.

In 1936, the Supreme Court struck down provisions of the Bituminous Coal Conservation Act of 1935, which delegated to certain producers and miners the power to fix maximum labor hours and minimum wages. The Court categorically stated that "a statute which attempts to confer such power undertakes an intolerable and unconstitutional interference with personal liberty and private property." *Carter* v. *Carter Coal Co.,* 298 U.S. 238, 311 (1936). The Court relied upon its earlier case, *Schechter Poultry Corporation* v. *United States,* wherein it had invalidated provisions relating to codes of fair competition, authorized to be approved by the President in his discretion "to effectuate the policy" of the Act. This delegation of law-making responsibility to private groups was found to be "unknown to our law and * * * utterly inconsistent with the constitutional prerogatives and duties of Congress." *Schechter Poultry Corp.,* at 537.

Nevertheless, expansion of private participation in the implementation of Federal legislation has occurred since the 1930's, and numerous examples may be cited wherein Congress has chosen to delegate responsibilities to private parties in all areas of powers that may be entrusted to the executive branch. Early examples of congressional delegations upheld by the High Court include *Currin* v. *Wallace,* 306 U.S. 1 (1939), wherein the Court sustained the constitutionality of a provision of the Tobacco Inspection Act of 1935 that denied judicial review of marketing orders adopted with the consent of handlers and farmers. The Court held that there was no unconstitutional delegation of power because "Congress ha[d] merely placed a restriction upon its own regulation by withholding its operation as to a given market 'unless two-thirds of the growers voting favor it.'" (See id. at 15–16. Similarly, in *Wickard* v. *Filburn,* 317 U.S. 111, 115–116 (1942), wheat and tobacco growers were empowered through referenda to accept or reject quotas or market designations). Under the Agricultural Marketing Agreement Act of 1937, Congress conditioned the effectiveness of the orders of the Secretary of Agriculture fixing the prices that handlers must pay to dairy farmers for milk products upon the approval in referenda by prescribed majorities of the handlers and producers in given areas. These provisions were sustained in *United States* v. *Rock Royal Cooperative,* 307 U.S. 533, 577–578 (1939) and *H.P. Hood & Sons* v. *United States,* 307 U.S. 588, 599–603 (1939).

The line of cases permitting delegations to private parties continues into modern times. Under the Beef Promotion and Research Act, as amended, an assessment is placed on cattle producers and importers, and the funds are turned over to a Cattlemen's Beef Promotion and Research Board and a Beef Promotion Operating Committee, which are charged with implementing the program. The Secretary of Agriculture selects members of the Board from lists furnished him by the designated units of producers and importers throughout the country, and the Committee is composed of ten members designated by the board and ten members from State beef councils, that is, entities organized pursuant to State statutes. All the programs are dependent upon referenda approval for their validity, and once approved, are binding on everyone, not just those who agree to participate. This scheme was upheld in *United States* v. *Frame,* 885 F.2d 1119 (3d Cir. 1989), cert. den., 1168 (1990).

Under the Occupational Safety and Health Act, Congress directed the Secretary of Labor to adopt interim occupational health and safety standards in particular areas developed by standards-producing private organizations, 29 U.S.C. §§ 652(9), 655(a), a delegation that was upheld in *Noblecraft Industries* v. *Secretary of Labor,* 614 F.2d 199 (9th Cir. 1980). A provision in the Medicare statute providing that hearings on disputed claims for Medicare payments be conducted by private insurance carriers, without a further right of appeal, was sustained in *Schweiker* v. *McClure,* 456 U.S. 188 (1982). A three-judge court upheld a congressional mandate in another portion of the Medicare statute that incorporated private professional standards review organizations into the process for denying reimbursements to providers where services are claimed to be "medically unnecessary." This delegation to the private organizations was upheld in *Association of American Physicians & Surgeons* v. *Weinberger,* 395 F. Supp. 125 (N.D.Ill.), aff'd. per curiam, 423 U.S. 975 (1975). See also *Corum* v. *Beth Israel Medical Center,* 373 F. Supp. 550, 551–553 (S.D.N.Y. 1974) (where the district court held that it was not unconstitutional for Congress to give veto power over the Secretary of Health, Education and Welfare's rulemaking authority to a now-defunct private entity called "the Federal Hospital Council.")

More recently, patients in a psychiatric hospital whose Medicare and Medicaid benefits were terminated when the hospital lost its accreditation by a private organization, and thus was de-certified by the Secretary of HHS under the Medicare and Medicaid programs, challenged the delegation of the accreditation responsibility to the private organization. The Third Circuit Court of Appeals found that the Secretary retained sufficient ultimate authority over decertification decisions resulting from loss of accreditation by a private entity to view the delegation as constitutional. *Cospito* v. *Heckler,* 742 F.2d 72 (3d Cir. 1984), cert. den., 471 U.S. 1131 (1985). This authority appeared to result from the Secretary's inherently broad discretion to adopt rules regarding psychiatric hospitals under the Medicare program. Thus, even though the statute defined inpatient psychiatric hospital services as "inpatient services which are provided in an institution which is accredited as a psychiatric hospital by the [Joint Commission on Accreditation of Hospitals]," the court held "that the Secretary has the authority to

make findings regarding the adequacy of a psychiatric hospital independent of the JCAH, and also has the authority to establish his own general standards by which those determinations are made." Id. at 89. In effect, the court viewed the actions of the private accreditation entity as subject to review by a public official under a Federal statute, and hence there was no impermissible delegation of legislative authority to a private party. See *Todd & Co.,* v. *SEC,* 557 F.2d 1008 (3d Cir. 1977) (in which the court found no unconstitutional delegation where the actions of private organizations were ultimately subject to review by a public agency.)

An unbroken line of precedents since the mid–1930's supports the conclusion that Congress may empower private-sector institutions to carry out functions under Federal law. While such delegations may not exist without some oversight by the executive branch, the non-delegation doctrine, per se, does not pose a bar to the inclusion of private parties in the execution of Federal legislation.

HEARINGS

The Subcommittee on Health and Environment held a legislative hearing on H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999, on September 22, 1999. The Subcommittee received testimony from: Dr. William Raub, Deputy Assistant Secretary for Planning and Evaluation/Science Policy, Department of Health and Human Services; Dr. William Payne, Director, Liver Transplant Program, Fairview Medical Center, Minneapolis, Minnesota; Dr. Robert D. Gibbons, Professor of Biostatistics, School of Medicine, Department of Psychiatry, University of Illinois at Chicago; Dr. Joshua Miller, Division of Transplantation, Department of Surgery, University of Miami School of Medicine, Miami, Florida; Mr. Craig Irwin, President, National Transplant Action Committee, Portland, Oregon; Dr. John M. Rabkin, Chief, Liver/Pancreas Transplantation Hepatobiliary Surgery, Oregon Health Sciences University, Portland, Oregon.

The Subcommittee on Health and Environment held a hearing entitled "Putting Patients First: Increasing Organ Supply for Transplantation," on April 15, 1999. The Subcommittee received testimony from Mr. Jamar Burton, Organ Transplant Recipient, State of Tennessee; Ms. Abbey Lynn Johnston, Organ Transplant Recipient, State of Ohio; Ms. Cynthia Guillemin, Organ Transplant Recipient, State of Florida; and Ms. Kara Grace Thio, Organ Transplant Recipient, State of North Carolina. Additional witnesses included Mr. John R. Campbell, Executive Director, LifeLink Foundation; Mr. Howard M. Nathan, President, Coalition on Donation, Delaware Valley Transplant Program, Philadelphia, Pennsylvania; Dr. Amadeo Marcos, Assistant Professor of Surgery, Medical College of Virginia, Richmond, Virginia; Dr. Joshua Miller, Division of Transplantation, Department of Surgery, University of Miami School of Medicine, Miami, Florida; Dr. John F. Neylan, President, American Society of Transplantation; Dr. Robert A. Metzger, Medical Director, Transplant Physician, Translife at Florida Hospital, Orlando, Florida; Dr. Robert S. D. Higgins, Director, Thoracic Organ Transplantation, Henry Ford Hospital, Detroit, Michigan;

and Mr. Joseph L. Brand, Chairman, National Kidney Foundation, Office of Scientific and Public Policy, Arlington, Virginia.

On June 18, 1998, the House Subcommittee on Health and Environment and the Senate Committee on Labor and Human Resources held a joint hearing entitled "Putting Patients First: Resolving Allocation of Transplant Organs." The Committees received testimony from The Honorable Robert G. Torricelli, U.S. Senator, State of New Jersey; The Honorable Louis Stokes, U.S. Representative, 11th Congressional District, State of Ohio; The Honorable Rick Santorum, U.S. Senator, Commonwealth of Pennsylvania; The Honorable Leonard L. Boswell, U.S. Representative, 3rd Congressional District, State of Iowa; The Honorable J. Robert Kerrey, U.S. Senator, State of Nebraska; The Honorable Karen Thurman, U.S. Representative, 5th Congressional District, State of Florida; The Honorable Ernest F. Hollings, U.S. Senator, State of South Carolina; The Honorable Bob Inglis, U.S. Representative, 4th Congressional District, State of South Carolina; The Honorable Thomas M. Barrett, U.S. Representative, 5th Congressional District State of Wisconsin; The Honorable Donna E. Shalala, Secretary, Department of Health and Human Services; Mr. Bruce Weir, President, Transplant Recipients International Organization, Inc.; Mr. Tom Meredith, Private Citizen, Antioch, Tennessee; Ms. Peggy Dreker, Private Citizen, Kearny, New Jersey; Dr. Lawrence G. Hunsicker, President, United Network for Organ Sharing, and Medical Director, Transplantation, University of Iowa Hospital and Clinic, Iowa City, Iowa; Dr. James F. Childress, Edwin B. Kyle Professor of Religious Studies and Medical Education, University of Virginia; Dr. Jorge D. Reyes, Director, Pediatric Transplantation Surgery, University of Pittsburgh Medical Center; Dr. Ron Busuttil, DuMont UCLA Transplant Center, UCLA Medical Center; Dr. Hector C. Ramos, Director of Liver Transplantation, Lifelink Transplant Institute, Tampa, Florida; Dr. Jeffrey C. Reese, Assistant Professor of Surgery, Director of Kidney-Pancreas Transplantation, University of Vermont; Dr. Clive O. Callender, Director, Howard University Transplant Center, Washington, D.C.; and Dr. William E. Harmon, Chief, Division of Nephrology, The Children's Hospital, Boston, Massachusetts.

COMMITTEE CONSIDERATION

On September 30, 1999, the Subcommittee on Health and Environment met in open markup session and approved H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999, for Full Committee consideration, amended, by a voice vote. On October 13, 1999, the Committee on Commerce met in open markup session and ordered H.R. 2418 reported to the House, amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following are the recorded votes on the motion to report H.R. 2418 and on amendments offered to

the measure, including the names of those Members voting for and against.

COMMITTEE ON COMMERCE -- 106TH CONGRESS
ROLL CALL VOTE # 14

BILL: H.R. 2418, Organ Procurement and Transplantation Network Amendments of 1999

MOTION: An Amendment by Mr. Klink, #4, to prohibit the Organ Procurement and Transplantation Network from expending revenue from fees on lobbying and other forms of First Amendment expression.

DISPOSITION: NOT AGREED TO by a roll call vote of 22 yeas to 25 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Bliley		X		Mr. Dingell	X		
Mr. Tauzin		X		Mr. Waxman	X		
Mr. Oxley		X		Mr. Markey	X		
Mr. Bilirakis		X		Mr. Hall	X		
Mr. Barton		X		Mr. Boucher			
Mr. Upton		X		Mr. Towns	X		
Mr. Stearns		X		Mr. Pallone	X		
Mr. Gillmor				Mr. Brown	X		
Mr. Greenwood		X		Mr. Gordon	X		
Mr. Cox		X		Mr. Deutsch	X		
Mr. Deal		X		Mr. Rush	X		
Mr. Largent		X		Ms. Eshoo	X		
Mr. Burr				Mr. Klink	X		
Mr. Bilbray		X		Mr. Stupak	X		
Mr. Whitfield				Mr. Engel	X		
Mr. Ganske		X		Mr. Sawyer	X		
Mr. Norwood		X		Mr. Wynn	X		
Mr. Coburn		X		Mr. Green	X		
Mr. Lazio		X		Ms. McCarthy	X		
Mrs. Cubin				Mr. Strickland	X		
Mr. Rogan		X		Ms. DeGette	X		
Mr. Shimkus		X		Mr. Barrett		X	
Mrs. Wilson		X		Mr. Luther	X		
Mr. Shadegg		X		Ms. Capps	X		
Mr. Pickering		X					
Mr. Fossella		X					
Mr. Blunt		X					
Mr. Bryant		X					
Mr. Ehrlich							

10/13/1999

COMMITTEE ON COMMERCE -- 106TH CONGRESS
VOICE VOTES
10/13/1999

BILL: H.R. 2418, Organ Procurement and Transplantation Network Amendments of 1999

AMENDMENT: An Amendment by Mr. Waxman, #1, to expand the role of the Secretary of Health and Human Services to include approval of policy determinations made by the Organ Procurement and Transplantation Network.

DISPOSITION: NOT AGREED TO by a voice vote.

AMENDMENT: An Amendment by Mr. Greenwood, #2, to add a section recognizing the importance of the organ donor family pledge.

DISPOSITION: AGREED TO by a voice vote.

AMENDMENT: An Amendment by Mr. Pallone, #3, to: (1) extend certification of all Organ Procurement Organizations for two additional years, and (2) mandate that any new rule-making include provisions for corrective action plans and due process for fair hearings and appeals.

DISPOSITION: AGREED TO by a voice vote.

MOTION: A motion by Mr. Bliley to order H.R. 2418 reported to the House, amended.

DISPOSITION: AGREED TO by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held legislative and oversight hearings and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 21, 1999.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Cyndi Dudzinski (for federal costs), and Leo Lex (for the state and local impact), and Jennifer Bullard (for the private-sector impact).

Sincerely,

BARRY B. ANDERSON
(For Dan L. Crippen, Director).

Enclosure.

H.R. 2418—Organ Procurement and Transplantation Network Amendments of 1999

Summary: H.R. 2418 would amend the National Organ Transplant Act of 1984 and reauthorize the Organ Procurement and

Transplantation Network activities administered by the Health Resources and Services Administration (HRSA). In 1999, a total of $10 million was appropriated for the organ procurement and transplant network, for the scientific registry, and for the purpose of increasing organ donation and procurement. In 2000, this legislation would authorize the appropriation of $6 million for the network and the registry and such sums as may be necessary for increasing organ donation and procurement. It would also authorize $5 million in new funding for travel and subsistence expenses incurred during living organ donation and $10 million for a program to educate the public and for studies and demonstrations designed to increase the rate of organ donation. It would authorize such sums as may be necessary for all these activities for 2001 through 2005.

Assuming appropriations of the necessary amounts, CBO estimates that implementing H.R. 2418 would cost $8 million in 2000 and a total of $101 million from 2000 through 2004, without adjusting for inflation, and $108 million if inflation adjustments are included. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

H.R. 2418 contains no private-sector or intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The bill would provide grants to states and other public and private entities that provide assistance to individuals for travel and subsistence expenses associated with the donation of living organs.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2418 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal years, in millions of dollars—				
	2000	2001	2002	2003	2004
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Without Adjustments for Inflation					
Estimated Authorization Level	26	26	26	26	26
Estimated Outlays	8	19	24	25	25
With Adjustment for Inflation					
Estimated Authorization Level	26	27	27	28	28
Estimated Outlays	8	19	24	27	27

Basis of estimate: For purposes of this estimate, CBO assumes that the bill will be enacted early in fiscal year 2000 and that outlays will follow historical spending rates for these activities. Where specified, CBO assumes the authorized and estimated amounts would be appropriated. The bill does not contain a specific authorization level for increasing organ donation and procurement, but instead would authorize the appropriation of such sums as may be necessary for 2000 through 2005. Based on the amount spent in the past for this activity, CBO estimates an authorization level of $5 million for 2000. The table shows two alternative spending paths: one assuming no increases to account for anticipated inflation, and one with annual inflation adjustments.

Pay-as-you-go considerations: None.

Intergovernmental and private-section impact: H.R. 2418 contains no private-sector or intergovernmental mandates as defined in UMRA. The bill would provide grants to states and other public and private entities that provide assistance to individuals for travel

and subsistence expenses associated with the donation of living organs.

Estimate prepared by: Federal Costs: Cyndi Dudzinski. Impact on State, local, and tribal governments: Leo Lex. Impact on the private sector: Jennifer Bullard.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the bill as the "Organ Procurement and Transplantation Network Amendments of 1999."

Section 2. Findings

Section 2 reports findings of the Congress related to the importance of the Organ Procurement and Transplantation Network (the Network) and the role of the Network in allocating scarce organs while promoting donation to increase organ supply.

Section 3. Organ Procurement and Transplantation Network

Section 3 amends section 372 of the Public Health Service Act (PHSA) to establish general and specific requirements for operating the Network.

Section 372(a) specifies requirements for continuing operation of the Network. Specifically, the Network must: (1) be a legal entity that is separate from the contracting organization; (2) include as its members organ procurement organizations, transplant centers, and other entities affiliated with organ donation and transplantation; and (3) have a Board of Directors (Board) that consults with Network participants to carry out its statutory responsibilities.

Section 372(a)(4)(A) requires the Network to include on its Board representatives of qualified organ procurement organizations, transplant centers, voluntary health associations, and members of the general public. A reasonable proportion of the Board membership must include patients who are on the waiting list to receive a transplant, or transplant recipients, or individuals who have donated an organ, or family members of patients, recipients, or donors.

Section 372(a)(4)(B) requires that the Board establish membership categories and qualifications for service on the Board, and authorizes the Board to have exclusive authority to admit individuals to its membership. Transplant surgeons and transplant physicians must comprise at least 50 percent of the membership of the Board. The Board is limited to a total of 42 members.

Section 372(a)(4)(C) requires that the Board have an executive committee and other appropriate committees.

Section 372(a)(4)(D) requires that the Board select the chair of each committee to ensure that there is continuity of leadership for the Board.

Section 372(b) establishes requirements for general functions of the Network. The Network must: (1) establish and operate a national system to match organs and individuals who need transplants, especially those individuals whose immune system makes it difficult for them to receive organs; (2) maintain one or more lists of patients who need organ transplants and operate the national system according to established medical criteria; (3) establish membership criteria for Network participants and medical criteria for listing patients and for allocating organs, and provide the public with an opportunity to comment on such criteria; (4) maintain the national system on a 24-hour basis using telephones and computers to facilitate organ matching among individuals on the waiting list; (5) assist organ procurement organizations in organ allocation, basing allocation on medical criteria established by the Network, and equity and ethics without regard to the economic status, political control, or influence of those awaiting an organ; (6) adopt quality standards for the acquisition and transportation of donated organs, including standards for preventing the transmission of infectious diseases; (7) prepare and distribute samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs; (8) coordinate the transportation of organs from organ procurement organizations to transplant centers; (9) work actively to increase organ donations; and (10) establish criteria, policies and procedures to address the disparity in mortality rates between children and adults while waiting for transplants.

Section 372(c) establishes requirements for the Scientific Registry.

Section 372(c)(1) requires that the Network maintain a scientific registry of patients who are waiting for an organ transplant, individuals who donate organs, and patients who receive organs for the purpose of an ongoing evaluation of the scientific and clinical status of organ transplantation. Section 372(c)(2) requires the Network to use scientific and clinical data from the Scientific Registry

to publish a report on the status of organ transplantation (as required in section 375).

Section 372(d) introduces new requirements related to the disclosure of information to Network participants and the general public.

Regarding requirements for information disclosure, section 372(d)(1) requires the Network to: (1) provide information to physicians and other health professionals on organ donation and transplantation; and (2) collect, analyze, and publish data on an annual basis on organ donation and transplantation.

Section 372(d)(2) describes the types of information that the Network must make available to patients. The Network must provide to patients information that is: (1) transplant-related, specific to transplant centers, and scientifically and clinically valid; (2) designed to assist patients and referring physicians in choosing a transplant center, including information on the supply of and demand for organs; and (3) with respect to the patient involved, include specific details about the transplant center, such as the probability of receiving an organ transplant at the center, the historical waiting time for receiving an organ transplant at the center, and the medical outcomes or survival rates for patients with similar medical conditions. In addition, subparagraph (D) requires the Network to provide information to patients by service areas, as defined by organ procurement organizations. In accordance with subparagraph (E) this information must be updated at least once a year.

Section 372(d)(3) requires that the Network publish and make available to the public an annual report on the overall status of organ procurement and transplantation.

Section 372(d)(4) prohibits the Network from releasing information, except for that authorized in paragraph (2) or (3). Unless authorized to do so by the patient or other entity in writing, the Network is prohibited from releasing information that permits: (1) the direct or indirect identification of persons on a waiting list for a transplant, organ transplant patients, donors or recipients; (2) the direct or indirect identification of any potential or actual organ donors; or (3) direct or indirect identification of participants in Network deliberations related to practitioner or institutional qualifications, due process proceedings or peer review activities. Exceptions to this prohibition apply to the release of information announcing final decisions of the Network. This paragraph may not be construed as prohibiting the disclosure of information within the Network, including information disclosed in the course of interactive organ sharing operations within the Network.

Section 372(e) requires that the Network carry out studies and demonstration projects.

Section 372(e)(1) requires that the Network carry out studies and projects designed to explore means for improving the process by which organs are procured and allocated, as well as ways to increase transplantation among populations with special needs or limited access, and among children.

Section 372(e)(2) directs the Network to consider a study on the transplantation of animal organs into humans (xenotransplantation) including the impact of applying alternate technologies for human transplantation.

Section 372(f) requires that the Network monitor the operations of Network participants in order to determine whether the Network participants are in compliance with statutory requirements for establishing medical criteria for organ allocation (required under subsection (b)(3)).

Section 372(g) establishes new requirements for peer review proceedings within the Network.

Section 372(g)(1) requires that the Network develop a peer review system for assuring that members of the Network comply with quality assurance criteria under subsection (b)(3).

Section 372(g)(2) mandates that the Network require as a condition of participation each Network participant to agree that the Network may, through a peer review process, require the participant to pay damages for the failure of the participant to comply with the criteria in subsection (b)(3). The Network must establish procedures to ensure that peer review proceedings are conducted in an impartial manner, with adequate opportunity for the Network participant to receive a hearing. The Network must identify various types of violations of such criteria and specify the maximum amount of damages that the Network may require a Network participant to pay for violations.

Section 372(g)(2)(B) permits the Network to restrict access to allocations of organs, if a Network participant has engaged in substantial violations of organ allocation criteria under subsection(b)(3).

Section 372(g)(2)(C) permits the Network to take actions to make the public aware of the extent to which a Network participant has been required to pay damages or has been the subject of restrictions in activities in organ allocation.

Section 372(g)(3) places restrictions on the release of data or information by the Network or the Secretary without the written permission of all parties involved if such data or information is related to peer review proceedings. If damages are required to be paid under paragraph (2) then the requirement may be publicly announced after the conclusion of the proceeding.

Section 372(h) establishes administrative provisions and procedural functions for the Network.

Section 372(h)(1) states that the amount of the contract for operating the Network, including the Scientific Registry, in any fiscal year may not exceed $6 million. The limitation does not apply to amounts provided for increasing organ donations.

Section 372(h)(2) clarifies the relationship between Secretary and the Network. The administrative and procedural functions of the Network are to be carried out in accordance with the mutual agreement of the Secretary and the Network. Functions that are scientific, clinical, or medical in nature are not administrative or procedural functions and are within the sole discretion of the Network. This section may not be construed as having any legal effect on the Medicare or Medicaid programs, except to the extent that section 1138 of the Social Security Act, or any other provision of such Act, provides otherwise.

Section 372(h)(3) establishes policy for non-Federal assets of the Network.

Section 372(h)(3)(A) states that no assets in the possession of the Network or revenues collected by the Network, other than amounts appropriated for the Network, shall be considered or be treated as Federal property, Federal revenues, or program funds pursuant to a Federal contract, nor shall such assets, revenues, or non-appropriated funds be subject to restriction or control by the Secretary. In addition, no member of the Network shall be required by the Secretary to pay any fees to the Network, nor shall the Secretary be authorized to collect or authorize collection of service fees with respect to the Network or the Scientific Registry.

Section 372(h)(3)(B) allows the Network to accept gifts of money or services for carrying out activities related to organ procurement and transplantation.

Section 372(h)(4) states that if any contract for the Network is awarded after the date of enactment, the Secretary must select an applicant to receive the contract from among applicants that have the written endorsement of a majority of the combined total number of transplant centers and qualified organ procurement organizations that are Network participants.

Section 372(h)(5) states that if the Secretary makes a determination to award the contract to a different contractor than the existing one, the Secretary must publish a notice to that effect in the Federal Register. The change can take effect no earlier than six months from the date of the notice. Such a change does not affect the membership status of any Network participant, or the membership status of any individual who serves on the Board.

Section 372(i) establishes requirements for additional procedures for oversight and public accountability. The Secretary must establish procedures for: (1) conducting public hearings and receiving comments from the public relating to the manner in which the Network is carrying out its duties under this section; (2) providing such comments to the Network and receiving responses from the Network; and (3) considering the public comments.

Section 372(j) includes requirements for evaluations by the Comptroller General of the United States.

Section 372(j)(1) directs the Comptroller to periodically conduct evaluations of the Network, including its structure and function and the relationship between the Secretary and the Network. The first evaluation must be completed no later than one year after enactment. Thereafter, periodical evaluations are due every second year.

Section 372(j)(2) requires that the Comptroller General, in conducting evaluations under paragraph (1), must consult with organizations that represent transplant surgeons, transplant physicians, transplant centers, organ procurement organizations, and other experts in the field of organ transplantation.

Section 372(j)(3) requires that the Network establish procedures for coordinating with the Comptroller General to carry out required evaluations.

Section 372(j)(4) requires that the Comptroller General report to Congress.

Section 372(j)(4)(A) requires that the Comptroller General prepare reports describing the findings of evaluations and submit such reports to the Committee on Commerce of the House of Representa-

tives and the Committee on Health, Education, Labor, and Pensions of the Senate.

Section 372(j)(4)(B) requires that the Network respond to the report of the Comptroller General, within 180 days of its publication, on actions it has taken in response to the evaluation issued by the Comptroller General.

Section 372(b) provides a rule of construction stating that the Act does not affect the duration of the existing contract that was in effect on the date of enactment of the Act.

Section 4. Additional amendments

Section 4 makes technical and conforming amendments to Part H of title III of the Public Health Service Act.

Section 5. Payment of travel and subsistence expenses incurred toward living organ donation

Section 5 establishes new section 376 in Part H of title III of the Public Health Service Act, as amended by 4(b) of this Act.

Section 376(a) permits the Secretary to make awards or grants for: (1) the payment of travel and expenses incurred by living organ donors; and (2) the payment of incidental non-medical expenses that the Secretary determines appropriate.

Section 376(b)(1) provides that the Secretary may make payments to living organ donors only if (1) the organ donor resides in a different State from that of the intended recipient, and (2) the annual income of the intended recipient does not exceed $35,000 (to be updated for inflation beginning in Fiscal Year 2001).

Section 376(b)(2) authorizes the Secretary to make exceptions to the eligibility requirements specified above. The Secretary may provide payment of travel and expenses for individuals who in good faith intend to, but do not, donate an organ. Also, the Secretary may provide for the expenses of one or more family members who accompany the organ donor.

Section 376(c)(1) requires that payment be limited to reasonable expenses that would be expected to travel to the vicinity of the transplant center nearest to the intended recipient.

Section 376(c)(2) defines the term, "covered vicinity" as the vicinity of the nearest transplant center to the residence of the intended recipient that regularly performs transplants of that type of organ.

Section 376(d) provides that the award made under subsection (a) will not be used to pay for the same expenses that have been paid for, or can reasonably be expected to be made by (1) any State compensation plan or Federal or State health benefits program, or (2) an entity that provides health services on a prepaid basis.

Section 376(e) makes reference to sections in the bill that define the terms, "covered vicinity," "donating individual," and "qualifying expenses."

Section 376(f) authorizes to be appropriated for this section a total of $5 million for each of Fiscal Years 2000 through 2005.

Section 6. Public awareness; studies and demonstrations

Section 6 adds new section 377 to Part H of title III of the Public Health Service Act.

Section 377(a) requires that the Secretary carry out a program to educate the public on organ donation, including the need to provide for an adequate rate for such donations.

Section 377(b) authorizes the Secretary to make grants to public and nonprofit private entities in order to carry out studies and demonstration projects for increasing organ donation.

Section 377(c) requires that the Secretary submit to Congress an annual report on public awareness activities, including observations about the extent to which the activities have affected organ donation.

Section 377(d)(1) authorizes to be appropriated a total of $10,000,000 for Fiscal Year 2000, and such sums as may be necessary for each of the Fiscal Years 2001 through 2005 for activities in section (6). The Secretary may not, for any one fiscal year, obligate more $2,000,000 for studies and demonstrations.

Section 7. Authorization of appropriations

Section 378(a) authorizes to be appropriated a total of $6 million for operation of the Network, including the Scientific Registry, for Fiscal Year 2000, and such sums as may be necessary for Fiscal Years 2001 through 2005.

Section 378(b) authorizes such sums as necessary for programs to increase organ donation and procurement as required in section 372 of the Act for each of the Fiscal Years 2000 through 2005.

Section 8. Effective date

Section 8 states that provisions of the Act become effective on the date of enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH

* * * * * * *

PART H—ORGAN TRANSPLANTS

ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. (a) * * *

(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

(A) * * *

* * * * * * *

(D) notwithstanding any other provision of law, has met the other requirements of this subsection and has been certified or recertified by the Secretary as meeting the performance standards to be a qualified organ procurement organization through a process which—

(i) granted certification or recertification within the previous 4 years with such certification in effect as of October 1, 1999, and remaining in effect through the earlier of—

(I) January 1, 2002, or

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

(ii) is defined through regulations promulgated by the Secretary not later than January 1, 2002, which—

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

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

(III) provide for the filing and approval of a corrective action plan by a qualified organ procurement organization that fails to meet the performance standards and a grace period of not less than 3 years during which such organization can implement the corrective action plan without risk of decertification; and

(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds;

[(D)] (*E*) has procedures to obtain payment for non-renal organs provided to transplant centers,

[(E)] (*F*) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

[(F)] (*G*) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

[(G)] (*H*) has a board of directors or an advisory board which—

(i) * * *

* * * * * * *

[ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

[SEC. 372. (a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year

may not exceed $2,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

[(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

[(A) be a private nonprofit entity that has an expertise in organ procurement and transplantation, and

[(B) have a board of directors—

[(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 371), transplant centers, voluntary health associations, and the general public; and

[(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

[(2) The Organ Procurement and Transplantation Network shall—

[(A) establish in one location or through regional centers—

[(i) a national list of individuals who need organs, and

[(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

[(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

[(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

[(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,

[(E) adopt and use standards of quality for the acquisition and transportation of donated organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

[(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

[(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

[(H) provide information to physicians and other health professionals regarding organ donation,

[(I) collect, analyze, and publish data concerning organ donation and transplants,

[(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation, and

[(K) work actively to increase the supply of donated organs.[1]

[(L) submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at

each transplant center affiliated with the organ procurement and transplantation network.

[(c) The Secretary shall establish procedures for—

[(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

[(2) the consideration by the Secretary of such critical comments.]

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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

(1) The Network shall be an independent, nonprofit private entity that is a separate legal entity from the entity to which such contract is awarded.

(2) The Network shall in accordance with criteria under subsection (b)(3) include as members qualified organ procurement organizations (as described in section 371(b)), transplant centers, and other entities that have a demonstrated interest in the fields of organ donation or transplantation. (Such members are in this section referred to as "Network participants".)

(3) The Network shall have a board of directors (in this section referred to as the "Board"). The Board shall, after consultation with Network participants, establish the policies for carrying out the functions described in this section for the Network.

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

(A) The Board shall include representatives of qualified organ procurement organizations, transplant centers, voluntary health associations, and the general public, including a reasonable proportion of the members of the Board who are patients awaiting a transplant or transplant recipients or individuals who have donated an organ or family members of patients, recipients or donors.

(B) The Board shall establish membership categories and qualifications with respect to serving on the Board, and shall have exclusive authority to admit individuals to membership on the Board. Transplant surgeons and transplant physicians shall comprise not less than 50 percent of the membership of the Board. The Board shall be limited to a total of 42 members.

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

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

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

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

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

(3) The Network shall establish criteria for being a Network participant, shall establish medical criteria for listing patients and for allocating organs, and shall provide to members of the public an opportunity to comment with respect to such criteria.

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

(5) The Network shall assist organ procurement organizations in the distribution of organs. The distribution of organs shall be based on medical criteria established by the Network, and also shall be based on equity and ethics without regard to economic status of those awaiting organ transplants and without political control or influence.

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

(7) The Network shall prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors.

(8) The Network shall coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers.

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

(10) The Network shall establish criteria, policies, and procedures to address the disparity in mortality rates between children and adults while waiting for organ transplants.

(c) SCIENTIFIC REGISTRY.—

(1) IN GENERAL.—The Network shall maintain a scientific registry of patients awaiting organ transplantation, persons from whom organs are removed for transplantation, and organ transplant recipients for the ongoing evaluation of the scientific and clinical status of organ transplantation.

(2) REPORTS.—The Network shall prepare for inclusion in the report under section 375 an analysis of scientifically and clinically valid information derived from the scientific registry under paragraph (1).

(d) INFORMATION AND DATA.—

(1) IN GENERAL.—The Network shall—

(A) provide information to physicians and other health professionals regarding organ donation and transplantation; and

(B) collect, analyze, and annually publish data concerning organ donation and transplantation.

(2) INFORMATION FOR PATIENTS AND GENERAL PUBLIC.—The Network shall make available to patients in need of organ transplants information in accordance with the following:

(A) The information shall be transplant-related information specific to transplant centers that are Network participants, which information has been determined by the Network to be scientifically and clinically valid.

(B) The information shall be designed to assist patients and referring physicians in choosing a transplant center, including information on the supply of and demand for organs.

(C) With respect to the patient involved, the information shall (taking into account patients in similar medical circumstances) include the following as applied to specific transplant centers:

(i) The probability of receiving an organ transplant.

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

(iii) Medical outcomes for similarly situated patients, which information shall be adjusted to reflect the medical risk factors for such patients.

(D) With respect to the patient involved, the information shall include the information described in subparagraph (C) as applied to the service areas of specific qualified organ procurement organizations (other than such areas in which there is only one transplant center).

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

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

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

(A) Information that permits direct or indirect identification of any patient who is waiting for a transplant, or who is an organ transplant patient or recipient of an organ.

(B) Information that permits direct or indirect identification of any potential or actual organ donors.

(C) Information that permits direct or indirect identification of participants in Network deliberations or determinations related to practitioner or institutional qualifications, due process proceedings or peer review activities, except for information announcing final decisions of the Network.

This paragraph may not be construed as prohibiting the disclosure of information within the Network, including information disclosed in the course of interactive organ sharing operations within the Network.

(e) STUDIES.—

(1) IN GENERAL.—The Network shall carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs or limited access to transplantation, and among children.

(2) CERTAIN TECHNOLOGIES.—The Network may study the impact of possible transplantation of animal organs (xenotransplantation) and other technologies to determine the impact upon, and prevent negative effects on, the fair and effective use of human allograft organs.

(f) QUALITY ASSURANCE; MONITORING OF NETWORK PARTICIPANTS.—The Network shall monitor the operations of Network participants to the extent appropriate for determining whether the participants are maintaining compliance with criteria under subsection (b)(3). In monitoring a Network participant under the preceding sentence, the Network shall inform the participant of any findings indicating noncompliance by the participant.

(g) QUALITY ASSURANCE; PEER REVIEW PROCEEDINGS.—

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

(2) NONCOMPLIANCE.—

(A) PAYMENT OF DAMAGES.—The Network shall require that, as a condition of being a Network participant, each such participant agree that the Network may, through a peer review proceeding under paragraph (1), require the participant to pay damages for the failure of the participant to comply with criteria under subsection (b)(3). The Network shall establish procedures to ensure that such proceedings are conducted in an impartial manner, with adequate opportunity for the Network participant involved to receive a hearing. The Network shall identify various types of violations of such criteria and specify the maximum amount of damages that the Network may under this subparagraph require a Network participant to pay for the type of violation involved.

(B) RESTRICTING ACCESS TO ALLOCATION SYSTEM.—If under subparagraph (A) it has been determined that a Network participant has engaged in substantial violations of criteria under subsection (b)(3), the Network may restrict the extent to which such participant is permitted to receive allocations of organs through the Network.

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

(3) CONFIDENTIALITY.—With respect to a peer review proceeding under paragraph (1), neither the Network nor the Secretary has authority to release data or information to the public relating to the proceedings without the written permission of all the parties involved, except that if damages under paragraph

(2) are required to be paid, the requirement may be publicly announced after the conclusion of the proceeding.

(h) ADMINISTRATIVE PROVISIONS.—

(1) LIMITATION ON AMOUNT OF CONTRACT.—The amount provided under a contract under subsection (a) in any fiscal year may not exceed $6,000,000 for the operation of the Network, including the scientific registry under subsection (c). Such limitation does not apply to amounts provided under the contract for increasing organ donation and procurement.

(2) RELATIONSHIP BETWEEN SECRETARY AND NETWORK.—The administrative and procedural functions described in this section for the Network shall be carried out in accordance with the mutual agreement of the Secretary and the Network. For purposes of the preceding sentence, functions that are scientific, clinical, or medical in nature are not administrative or procedural functions and are within the sole discretion of the Network. With respect to the programs under titles XVIII and XIX of the Social Security Act, this section may not be construed as having any legal effect on such programs, except to the extent that section 1138 of such Act, or any other provision of such Act, provides otherwise.

(3) NONFEDERAL ASSETS OF NETWORK.—

(A) IN GENERAL.—No assets in the possession of the Network or revenues collected by the Network, other than amounts appropriated under section 378, shall be considered or be treated as Federal property, Federal revenues, or program funds pursuant to a Federal contract, nor shall such assets, revenues, or nonappropriated funds be subject to restriction or control by the Secretary, nor shall any member of the Network be required by the Secretary to pay any fees to the Network, nor shall the Secretary be authorized to collect or authorize collection of service fees with respect to the Network or the scientific registry under subsection (c).

(B) GIFTS.—This section does not prohibit the Network from accepting gifts of money or services, including gifts to carry out activities to provide for an increase in the rate of organ donation.

(4) COMMUNITY ENDORSEMENT OF CONTRACT RECIPIENT.—In the case of any contract under subsection (a) that is awarded after the date of the enactment of the Organ Procurement and Transplantation Network Amendments of 1999, the Secretary shall select an applicant to receive the contract from among applicants that have the written endorsement of a majority of the combined total number of transplant centers and qualified organ procurement organizations that are Network participants (without regard to whether such centers or organizations endorse more than one applicant for the contract).

(5) CHANGE IN CONTRACT RECIPIENT.—With respect to the expiration of the period during which a contract under subsection (a) is in effect, if the Secretary makes a determination to award the contract to a different entity than the entity to which the previous contract under such subsection was awarded, the Secretary shall publish in the Federal Register a notice that such

change in the administration of the Network will take place, and the change may not take effect any sooner than the expiration of the six-month period beginning on the date on which the notice is so published. Such a change does not affect the membership status of any Network participant, or the membership status of any individual who serves on the Board (other than any membership position that is predicated solely on being a representative of the current contractor under subsection (a)).

(i) ADDITIONAL PROCEDURES REGARDING OVERSIGHT AND PUBLIC ACCOUNTABILITY.—For purposes of providing oversight of and public accountability for the operation of the Network, the Secretary shall establish procedures for—

(1) conducting public hearings and receiving from interested persons comments regarding criteria of the Network and critical comments relating to the manner in which the Network is carrying out its duties under this section;

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

(3) the consideration by the Secretary of such comments.

(j) EVALUATIONS BY GENERAL ACCOUNTING OFFICE.—

(1) IN GENERAL.—The Comptroller General of the United States shall periodically conduct evaluations of the Network, including the structure and function of the Network and the relationship between the Secretary and the nonprofit private entity that under subsection (a) operates the Network. The first such evaluation shall be completed not later than one year after the date of the enactment of the Organ Procurement and Transplantation Network Amendments of 1999, and such an evaluation shall be completed not later than every second year thereafter.

(2) INPUT FROM FIELD.—In conducting evaluations under paragraph (1), the Comptroller General shall consult with organizations that represent transplant surgeons, transplant physicians, transplant centers, and qualified organ procurement organizations, and with other experts in the field of organ transplantation, including experts who are not members of the Board of the Network or of the executive structure of the contractor under subsection (a) .

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

(4) REPORTS TO CONGRESS.—

(A) COMPTROLLER GENERAL.—The Comptroller General shall prepare reports describing the findings of evaluations under paragraph (1) and shall submit such reports to the Committee on Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate. The Comptroller General shall provide a copy of each such report to the Network.

(B) NETWORK.—Not later than 180 days after the date on which a report is submitted under subparagraph (A), the Network shall submit to each of the committees specified in such subparagraph a report describing any actions the Net-

work has taken in response to the report under subparagraph (A).

[SCIENTIFIC REGISTRY

[SEC. 373. The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 an analysis of information derived from the registry.]

GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

SEC. [374.] *373.* (a) * * *

(b)(1) A grant for planning under section 371(a)(1) may be made for one year with respect to any organ procurement organization *and other organizations for the purpose of increasing the supply of transplantable organs* and may not exceed $100,000.

* * * * * * *

(c)(1) The Secretary shall determine the amount of a grant or contract made under section 371 [or 373]. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)(A) Each recipient of a grant or contract under section 371 [or 373] shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under section 371 [or 373] that are pertinent to such grant or contract.

(d) For purposes of this part:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

[(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 373, such term includes bone marrow.]

(2) The term "organ", with respect to transplantation into humans, means the human or other animal kidney, liver, heart, lung, pancreas, and any other organ (other than human corneas and eyes) specified by the Secretary by regulation. For purposes of section 372(c), such term includes bone marrow.

ADMINISTRATION

SEC. [375.] *374.* The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this [part] *section* and coordinate with the organ procurement activities under title XVIII of the Social Security Act,

* * * * * * *

(4) provide information—

[(i)] *(A)* to patients, their families, and their physicians about transplantation; and

[(ii)] *(B)* to patients and their families about the resources available nationally and in each State, and the [comparative costs and patient outcomes] *comparative patient outcomes* at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

REPORT

SEC. [376.] *375.* Not later than February 10 of 1991 and of each second year thereafter, [the Secretary] *the Organ Procurement and Transplantation Network under section 372* shall publish, and submit to the [Committee on Energy and Commerce] *Committee on Commerce* of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

[SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.

[(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining—

[(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;

[(2) the problems encountered in the procurement and allocation; and

[(3) the effect of State required-request laws.

[(b) REPORT.—Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.]

PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES INCURRED TOWARD LIVING ORGAN DONATION

SEC. 376. (a) IN GENERAL.—The Secretary may make awards of grants or contracts to States, transplant centers, qualified organ procurement organizations under section 371, or other public or private entities for the purpose of—

(1) providing for the payment of travel and subsistence expenses incurred by individuals toward making living donations

of their organs (in this section referred as "donating individuals"); and

(2) in addition, providing for the payment of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

(b) ELIGIBILITY.—

(1) IN GENERAL.—Payments under subsection (a) may be made for the qualifying expenses of a donating individual only if—

(A) the State in which the donating individual resides is a different State than the State in which the intended recipient of the organ resides; and

(B) the annual income of the intended recipient of the organ does not exceed $35,000 (as adjusted for fiscal year 2001 and subsequent fiscal years to offset the effects of inflation occurring after the beginning of fiscal year 2000).

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

(A) The Secretary may consider the term "donating individuals" as including individuals who in good faith incur qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs.

(B) The Secretary may consider the term "qualifying expenses" as including the expenses of having one or more family members of donating individuals accompany the donating individuals for purposes of subsection (a) (subject to making payment for only such types of expenses as are paid for donating individuals).

(c) LIMITATION ON AMOUNT OF PAYMENT.—

(1) IN GENERAL.—With respect to the geographic area to which a donating individual travels for purposes of subsection (a), if such area is other than the covered vicinity for the intended recipient of the organ, the amount of qualifying expenses for which payments under such subsection are made may not exceed the amount of such expenses for which payment would have been made if such area had been the covered vicinity for the intended recipient, taking into account the costs of travel and regional differences in the costs of living.

(2) COVERED VICINITY.—For purposes of this section, the term "covered vicinity", with respect to an intended recipient of an organ from a donating individual, means the vicinity of the nearest transplant center to the residence of the intended recipient that regularly performs transplants of that type of organ.

(d) RELATIONSHIP TO PAYMENTS UNDER OTHER PROGRAMS.—An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

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

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

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

(1) The term "covered vicinity" has the meaning given such term in subsection (c)(2).

(2) The term "donating individuals" has the meaning indicated for such term in subsection (a)(1), subject to subsection (b)(2)(A).

(3) The term "qualifying expenses" means the expenses authorized for purposes of subsection (a), subject to subsection (b)(2)(B).

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

PUBLIC AWARENESS; STUDIES AND DEMONSTRATIONS

SEC. 377. (a) PUBLIC AWARENESS.—The Secretary shall (directly or through grants or contracts) carry out a program to educate the public with respect to organ donation, including the need to provide for an adequate rate of such donations.

(b) STUDIES AND DEMONSTRATIONS.—The Secretary may make grants to public and nonprofit private entities for the purpose of carrying out studies and demonstration projects with respect to providing for an adequate rate of organ donation.

(c) ANNUAL REPORT TO CONGRESS.—The Secretary shall annually submit to the Congress a report on the activities carried out under this section, including provisions describing the extent to which the activities have affected the rate of organ donation.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2005. Such authorization of appropriations is in addition to any other authorizations of appropriations that is available for such purpose.

(2) STUDIES AND DEMONSTRATIONS.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may not obligate more than $2,000,000 for carrying out subsection (b).

[SEC. 378. AUTHORIZATION OF APPROPRIATIONS.

[For the purpose of carrying out this part, there are authorized to be appropriated $8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.]

AUTHORIZATION OF APPROPRIATIONS FOR ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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

(b) INCREASING ORGAN DONATION AND PROCUREMENT.—For the purpose of increasing organ donation and procurement through the Organ Procurement and Transplantation Network under section 372, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2000 through 2005. Such authorization of appropriations is with respect to such purpose in addition to the authorization of appropriations established in subsection (a).

* * * * * * *

DISSENTING VIEWS

H.R. 2418 overturns the principles which have governed the Nation's organ allocation system for fifteen years. The bill raises fatal constitutional concerns and irresponsibly inverts the roles of the Federal government and its contractor. In the end, H.R. 2418 poses a threat to the hopes and health of transplant patients and their families.

The National Organ Transplant Act of 1984 (NOTA) created the Organ Procurement and Transplantation Network (OPTN), a national organ allocation system overseen by the Secretary of Health and Human Services. Congress created the OPTN because "[a]n equitable policy and system is necessary so that individuals throughout our country can have access to organ transplantation when appropriate and necessary."

Since 1984, Congress has emphasized repeatedly that the OPTN should serve all Americans as equitably as possible. The Organ Transplant Amendments Act of 1987 recognized that the OPTN was created "in order to facilitate an equitable allocation of organs" across the country. In the Transplant Amendments Act of 1990, Congress stressed that the OPTN was to assist "in the nationwide distribution of organs equitably among transplant patients." In 1996, the Senate passed a bipartisan NOTA reauthorization bill by unanimous consent, only to have this Committee fail to act on this important legislation. The Senate advised this Committee—

> The original intent of the National Organ Transplant Act was to assure patients that no matter who they were or where they lived, they would have a fair chance of receiving an organ transplant. It is the belief of the committee that the United States should adopt a consistent and fair system of allocation and move away from the persistent fragmentation and inconsistency that may have evolved despite the National Organ Transplant Act.

In furthering the goal of a "consistent and fair system of allocation," the Secretary published the Final Rule governing the OPTN on April 2, 1998. Because of the OPTN's failure to remedy geographical and ethnic inequities across the country, the Final Rule calls for more equitable sharing of organs and for uniform, objective criteria for patient listing. As the Final Rule states, it "does not establish specific allocation policies, but instead looks to the organ transplant community to take action to meet the performance goals."

We believe this approach to be wholly consistent with the intent of Congress. Allocation policies must be developed "bottom up" through the expertise and experience of patients and practitioners. But the Secretary is given oversight authority to ensure those policies reflect the public interest. When those policies fail to achieve

the ends envisioned by Congress, as they are failing today, the Secretary plays an indispensable role in correcting these failures.

The Final Rule has been supported by the major transplant patient organizations, including the American Liver Foundation, Transplant Recipients International Organization and the National Transplant Action Committee. But the efforts of the current OPTN contractor, the United Network for Organ Sharing (UNOS), to derail the Final Rule have had a corrosive effect on public confidence in the organ allocation system. Misinformation has been spread to frighten patients, communities of color, and the poor. Patient listing fees which should have been expended on health care have been squandered on a lobbying and public relations campaign.

The result has been genuine harm to the public health. The organ allocation system is an inequitable patchwork of ad hoc sharing or parochial hoarding. Patients live or die based on where they live—not on how sick they are. African Americans and the poor continue to face disproportionate barriers to referrals, waiting lists, and transplants. Most recently, states including Louisiana, Texas and Wisconsin have enacted hoarding laws intended to impede organ sharing. And to crown this dismal record, a one-year moratorium on the Final Rule's implementation was enacted in the Omnibus Appropriations Act of 1999 (P.L. 105–277).

The provision which blocked the Final Rule also mandated an Institute of Medicine (IOM) study of the organ procurement and transplantation system. The study advocates major changes in the organ allocation system and endorses active oversight by the Secretary. The IOM "recommends that the DHHS Final Rule be implemented" because broader sharing "will result in more opportunities to transplant sicker patients without adversely affecting less sick patients." The study dismisses claims that donation rates would suffer or small transplant centers would close under the Final Rule.

Perhaps most importantly, the IOM cites the need for strong federal oversight of the allocation system, concluding—

> The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the Final Rule, to manage the system of organ procurement and transplantation in the public interest.

In contrast, H.R. 2418 completely eliminates meaningful oversight of the OPTN. It divests the Secretary of any authority to require anything of the OPTN. Functions of a "scientific, clinical, or medical" nature would be in the "sole discretion" of the OPTN. As the bill's sponsors readily acknowledge, this encompasses practically everything of meaning, including the Nation's organ allocation and transplantation policies.

Moreover, any changes to those few minor "administrative and procedural functions" remaining under the Secretary's purview would require the "mutual agreement" of the Secretary and the OPTN. H.R. 2418 advances the absurd proposition that the OPTN should exercise an absolute veto over any proposed changes to the organ allocation system, whether they affect the number of organs it allocates or the number of paper clips it purchases. Indeed, were H.R. 2418 to become law, nothing short of an act of Congress would

serve to alter the nation's organ allocation system in the absence of the OPTN's autocratic consent.

The fallacy of shielding the OPTN from accountability and oversight by the Secretary is compounded, in the view of the Department of Justice, by "significant constitutional concerns involving the separation of powers." In creating an unregulated monopoly affecting the lives and health of Americans, the Department regards H.R. 2418 as an unconstitutional delegation of authority to a private entity because it "goes beyond * * * permissible forms of legislation by actually giving to a private organization regulatory authority unfettered by executive involvement."

Were H.R. 2418 to become law and somehow survive constitutional challenge, it would fail to accomplish what its sponsors claim they desire—insulate the organ allocation system from politics and bureaucrats. By eliminating Secretarial oversight, H.R. 2418 simply invests private bureaucrats with absolute life-and-death authority and the freedom to exercise it in settling their institutional disputes or professional rivalries.

H.R. 2418 is also silent regarding state laws. The sponsors acknowledge that a state law would prevail in a conflict with the OPTN's policies—ensuring inevitable conflicts with state hoarding laws and other statutes affecting the availability of organs. But in liberating the OPTN from what the sponsors perceive to be the burden of Secretarial oversight, they condemn it to a certain 'death of a thousand cuts' from conflicting state mandates.

The bill would exacerbate a perennial problem with UNOS. Public knowledge about the performance of the OPTN has been limited because of restrictions UNOS placed on access to essential patient outcome data. For many years, the Department faced fierce resistance to its efforts to obtain such data from its own contractor. Only in the past few weeks did UNOS make 5-year-old, transplant center-specific data available to the public.

This week, at the request of members of this Committee, the Department released a report providing up-to-date patient outcome data for the first time on more than 100 transplant centers across the country. The data revealed "a wide variation in center-specific outcomes," including a three-fold difference in the chances of getting a liver or heart transplant at centers farthest from the national average. The odds of dying while on the waiting list varied by 300 percent for liver patients and 250 percent for heart patients.

Such data should have already been available to the public. But in order to compel UNOS to disclose the data analyzed by the Department, Congress had to enact a law at the time the moratorium on the Final Rule was enacted. Under H.R. 2418, however, such data would only be available to a narrow category of listed patients—not to the public or the Secretary. The bill would thus enable the OPTN to conceal vital data from public scrutiny.

H.R. 2418 is also laden with measures blatantly intended to protect UNOS, the incumbent contractor, from competition. For example, the bill provides that a new contractor selected by the Secretary must also meet with the "written endorsement of a majority" of the OPTN's members. Such a requirement makes a mockery of bidding out an essential government contract, and is inconsistent with the Federal Acquisition Regulation, which mandates competition in all government contracts.

H.R. 2418 has other serious substantive flaws, but of those remaining, the most troubling must be the manner in which it opens the organ allocation system to potential financial abuses. Donated organs are the 'gift of life,' not commodities. Yet the bill as introduced would have emasculated our country's long-standing ban on the sale of organs.

The bill also dispenses with any limits to the OPTN's "accepting gifts of money or services." It is silent about what potential influence such gifts might have on a patient's status on a waiting list. It fails to bar preferential treatment on the basis of such gifts. While "economic status" is a prohibited factor in allocation decisions, "gifts" are not.

Finally, H.R. 2418 includes an additional carve-out of the OPTN's finances from Secretarial oversight. Nonappropriated revenue, such as patient listing fees, would be free from "restriction or control by the Secretary." Patients have no choice in paying the listing fees. If they do not, they have no chance of receiving a transplant. The bill would allow UNOS or its successor to set those fees as high as they wished, and use those monies for any purpose, including lobbying or other political activities. Under H.R. 2418, the Secretary and the public would be unable to stop this misuse of funds.

Despite its many flaws and unsound foundation, H.R. 2418 is most dangerous as a blunt political instrument, not as prospective law. The Secretary of Health and Human Services has already written this Committee that she would recommend the President veto the bill in its present form. The Department of Justice has written of its profound constitutional defects. Instead, H.R. 2418 is primarily intended to provide momentum to the legislative effort to extend a moratorium on the Final Rule.

On October 18 the Secretary fulfilled her commitment to revise the Final Rule to account for many of the concerns raised by the IOM report, UNOS and other stakeholders. We believe that implementation of the revised regulation should be allowed to proceed. We are ever hopeful that a variety of factors will come together and compromise will be achieved. The moratorium will expire imminently. Even UNOS has adopted broader organ sharing policies, albeit in an effort to preempt the Final Rule. Our hope is that such progress will benefit patients and simply render the extreme provisions of H.R. 2418 irrelevant.

JOHN D. DINGELL.
RON KLINK.
BOBBY L. RUSH.
EDOLPHUS TOWNS.
HENRY A. WAXMAN.
ALBERT R. WYNN.
TED STRICKLAND.
SHERROD BROWN.
TOM SAWYER.
EDWARD J. MARKEY.

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