

Public Law 98-507

98th Congress

An Act

To provide for the establishment of the Task Force on Organ Transplantation and the Organ Procurement and Transplantation Network, to authorize financial assistance for organ procurement organizations, and for other purposes.

Oct. 19, 1984

[S. 2048]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Organ Transplant Act".

National Organ
Transplant Act.
42 USC 201 note.
Health.

TITLE I—TASK FORCE ON ORGAN PROCUREMENT AND TRANSPLANTATION

ESTABLISHMENT AND DUTIES OF TASK FORCE

SEC. 101. (a) Not later than ninety days after the date of the enactment of this Act, the Secretary of Health and Human Services (hereinafter in this title referred to as the "Secretary") shall establish a Task Force on Organ Transplantation (hereinafter in this title referred to as the "Task Force").

42 USC 273 note.

(b)(1) The Task Force shall—

(A) conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation,

(B) prepare the assessment described in paragraph (2) and the report described in paragraph (3), and

(C) advise the Secretary with respect to the development of regulations for grants under section 371 of the Public Health Service Act.

Post, p. 2342.

(2) The Task Force shall make an assessment of immunosuppressive medications used to prevent organ rejection in transplant patients, including—

(A) an analysis of the safety, effectiveness, and costs (including cost-savings from improved success rates of transplantation) of different modalities of treatment;

(B) an analysis of the extent of insurance reimbursement for long-term immunosuppressive drug therapy for organ transplant patients by private insurers and the public sector;

(C) an identification of problems that patients encounter in obtaining immunosuppressive medications; and

(D) an analysis of the comparative advantages of grants, coverage under existing Federal programs, or other means to assure that individuals who need such medications can obtain them.

(3) The Task Force shall prepare a report which shall include—

Report.

(A) an assessment of public and private efforts to procure human organs for transplantation and an identification of factors that diminish the number of organs available for transplantation;

(B) an assessment of problems in coordinating the procurement of viable human organs including skin and bone;

(C) recommendations for the education and training of health professionals, including physicians, nurses, and hospital and emergency care personnel, with respect to organ procurement;

(D) recommendations for the education of the general public, the clergy, law enforcement officers, members of local fire departments, and other agencies and individuals that may be instrumental in effecting organ procurement;

(E) recommendations for assuring equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant;

(F) an identification of barriers to the donation of organs to patients (with special emphasis upon pediatric patients), including an assessment of—

(i) barriers to the improved identification of organ donors and their families and organ recipients;

(ii) the number of potential organ donors and their geographical distribution;

(iii) current health care services provided for patients who need organ transplantation and organ procurement procedures, systems, and programs which affect such patients;

(iv) cultural factors affecting the family with respect to the donation of the organs; and

(v) ethical and economic issues relating to organ transplantation needed by chronically ill patients;

(G) recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of organs;

(H) an analysis of the factors involved in insurance reimbursement for transplant procedures by private insurers and the public sector;

(I) an analysis of the manner in which organ transplantation technology is diffused among and adopted by qualified medical centers, including a specification of the number and geographical distribution of qualified medical centers using such technology and an assessment of whether the number of centers using such technology is sufficient or excessive and of whether the public has sufficient access to medical procedures using such technology; and

(J) an assessment of the feasibility of establishing, and of the likely effectiveness of, a national registry of human organ donors.

MEMBERSHIP

42 USC 273 note.

SEC. 102. (a) The Task Force shall be composed of twenty-five members as follows:

(1) Twenty-one members shall be appointed by the Secretary of which:

(A) nine members shall be physicians or scientists who are eminent in the various medical and scientific specialties related to human organ transplantation;

(B) three members shall be individuals who are not physicians and who represent the field of human organ procurement;

(C) four members shall be individuals who are not physicians and who as a group have expertise in the fields of law,

theology, ethics, health care financing, and the social and behavioral sciences;

(D) three members shall be individuals who are not physicians or scientists and who are members of the general public; and

(E) two members shall be individuals who represent private health insurers or self-insurers.

(2) The Surgeon General of the United States, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Administrator of the Health Care Financing Administration shall be ex officio members.

(b) No individual who is a full-time officer or employee of the United States may be appointed under subsection (a)(1) to the Task Force. A vacancy in the Task Force shall be filled in the manner in which the original appointment was made. A vacancy in the Task Force shall not affect its powers.

(c) Members shall be appointed for the life of the Task Force.

(d) The Task Force shall select a Chairman from among its members who are appointed under subsection (a)(1).

(e) Thirteen members of the Task Force shall constitute a quorum, but a lesser number may hold hearings.

(f) The Task Force shall hold its first meeting on a date specified by the Secretary which is not later than thirty days after the date on which the Secretary establishes the Task Force under section 101. Thereafter, the Task Force shall meet at the call of the Chairman or a majority of its members, but shall meet at least three times during the life of the Task Force.

(g)(1) Each member of the Task Force who is not an officer or employee of the United States shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule under section 5332 of title 5, United States Code, for each day (including traveltime) during which such member is engaged in the actual performance of duties as a member of the Task Force. Each member of the Task Force who is an officer or employee of the United States shall receive no additional compensation.

(2) While away from their homes or regular places of business in the performance of duties for the Task Force, all members of the Task Force shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under sections 5702 and 5703 of title 5, United States Code.

SUPPORT FOR THE TASK FORCE

SEC. 103. (a) Upon request of the Task Force, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Task Force to assist the Task Force in carrying out its duties under this Act.

42 USC 273 note.

(b) The Secretary shall provide the Task Force with such administrative and support services as the Task Force may require to carry out its duties.

REPORT

SEC. 104. (a) The Task Force may transmit to the Secretary, the Committee on Labor and Human Resources of the Senate, and the

42 USC 273 note.

- Report. Committee on Energy and Commerce of the House of Representatives such interim reports as the Task Force considers appropriate.
- (b) Not later than 7 months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives on its assessment under section 101(b)(2) of immunosuppressive medications used to prevent organ rejection.
- Report. (c) Not later than twelve months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a final report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives. The final report of the Task Force shall include—
- (1) a description of any findings and conclusions of the Task Force made pursuant to any examination conducted under section 101(b)(1)(A),
 - (2) the matters specified in section 101(b)(3), and
 - (3) such recommendations as the Task Force considers appropriate.

TERMINATION

- 42 USC 273 note. SEC. 105. The Task Force shall terminate three months after the date on which the Task Force transmits the report required by section 104(c).

TITLE II—ORGAN PROCUREMENT ACTIVITIES

SEC. 201. Part H of title III of the Public Health Service Act is amended to read as follows:

“PART H—ORGAN TRANSPLANTS

“ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

- Grants.
42 USC 273. “SEC. 371. (a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).
- “(2) The Secretary may make grants for the establishment, initial operation, and expansion of qualified organ procurement organizations described in subsection (b).
- “(3) In making grants under paragraphs (1) and (2), the Secretary shall—
- “(A) take into consideration any recommendations made by the Task Force on Organ Transplantation established under section 101 of the National Organ Transplant Act, and
- “(B) give special consideration to applications which cover geographical areas which are not adequately served by organ procurement organizations.
- “(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) is a nonprofit entity,
- Ante*, p. 2339.

"(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

"(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys,

42 USC 1395.

"(D) has procedures to obtain payment for non-renal organs provided to transplant centers,

"(E) has a defined service area which is a geographical area of sufficient size which (unless the service area comprises an entire State) will include at least fifty potential organ donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,

"(F) 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) has a board of directors or an advisory board which—

"(i) is composed of—

"(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

"(II) members who represent the public residing in such area,

"(III) a physician with knowledge, experience, or skill in the field of histocompatibility,

"(IV) a physician with knowledge or skill in the field of neurology, and

"(V) from each transplant center in its service area which has arrangements described in paragraph (2)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

"(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (2), and

"(iii) has no authority over any other activity of the organization.

"(2) An organ procurement organization shall—

"(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

"(B) conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,

"(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 372(b)(2)(D),

"(D) arrange for the appropriate tissue typing of donated organs,

"(E) have a system to allocate donated organs among transplant centers and patients according to established medical criteria,

"(F) provide or arrange for the transportation of donated organs to transplant centers,

"(G) have arrangements to coordinate its activities with transplant centers in its service area,

"(H) participate in the Organ Procurement Transplantation Network established under section 372,

"(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors, and

"(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs.

Appropriation
authorization.

"(c) For grants under subsection (a) there are authorized to be appropriated \$5,000,000 for fiscal year 1985, \$8,000,000 for fiscal year 1986, and \$12,000,000 for fiscal year 1987.

"ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

42 USC 274.

"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 which is not engaged in any activity unrelated to organ procurement, and

"(B) have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 371), transplant centers, voluntary health associations, and the general public.

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

"(C) assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations,

"(D) adopt and use standards of quality for the acquisition and transportation of donated organs,

"(E) prepare and distribute, on a regionalized 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,

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

"(G) provide information to physicians and other health professionals regarding organ donation, and

"(H) collect, analyze, and publish data concerning organ donation and transplants.

"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.

42 USC 274a.

"GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

"SEC. 374. (a) No grant may be made under section 371 or 373 or contract entered into under section 372 or 373 unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

Grants.
42 USC 274b.

"(b)(1) In considering applications for grants under section 371—

"(A) the Secretary shall give priority to any applicant which has a formal agreement of cooperation with all transplant centers in its proposed service area,

"(B) the Secretary shall give special consideration to organizations which met the requirements of section 371(b) before the date of the enactment of this section, and

"(C) the Secretary shall not discriminate against an applicant solely because it provides health care services other than those related to organ procurement.

The Secretary may not make a grant for more than one organ procurement organization which serve the same service area.

Prohibition.

"(2) A grant for planning under section 371 may be made for one year with respect to any organ procurement organization and may not exceed \$100,000.

"(3) Grants under section 371 for the establishment, initial operation, or expansion of organ procurement organizations may be made for two years. No such grant may exceed \$500,000 for any year and no organ procurement organization may receive more than \$800,000 for initial operation or expansion.

"(c)(1) The Secretary shall determine the amount of a grant made under section 371 or 373. Payments under such grants 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.

"(2)(A) Each recipient of a grant 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, the total cost of the undertaking in connection with which such grant was made, and the amount of that

Records.

portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

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 under section 371 or 373 that are pertinent to such grant.

"(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.

"ADMINISTRATION

42 USC 274c.

"SEC. 375. The Secretary shall, during fiscal years 1985, 1986, 1987, and 1988, designate and maintain an identifiable administrative unit in the Public Health Service to—

42 USC 1395.

Public
information.

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

"(2) conduct a program of public information to inform the public of the need for organ donations,

"(3) provide technical assistance to organ procurement organizations receiving funds under section 371, the Organ Procurement and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants, and

Report.

"(4) one year after the date on which the Task Force on Organ Transplantation transmits its final report under section 104(c) of the National Organ Transplant Act, and annually thereafter through fiscal year 1988, submit to Congress an annual report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.

"REPORT

42 USC 274d.

"SEC. 376. The Secretary shall annually publish 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."

TITLE III—PROHIBITION OF ORGAN PURCHASES

Penalties.

42 USC 274e.

SEC. 301. (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.

(b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.

(c) For purposes of subsection (a):

(1) The term "human organ" means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin,

and any other human organ specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term "interstate commerce" has the meaning prescribed for it by section 201(b) of the Federal Food, Drug and Cosmetic Act.

21 USC 321.

TITLE IV—MISCELLANEOUS

BONE MARROW REGISTRY DEMONSTRATION AND STUDY

SEC. 401. (a) Not later than nine months after the date of enactment of this Act, the Secretary of Health and Human Services shall hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors.

42 USC 273 note.

(b) If the conference held under subsection (a) finds that it is feasible to establish a national registry of voluntary donors of bone marrow and that such a registry is likely to be effective in matching donors with recipients, the Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall, for purposes of the study under subsection (c), establish a registry of voluntary donors of bone marrow. The Secretary shall assure that—

(1) donors of bone marrow listed in the registry have given an informed consent to the donation of the bone marrow; and

(2) the names of the donors in the registry are kept confidential and access to the names and any other information in the registry is restricted to personnel who need the information to maintain and implement the registry, except that access to such other information shall be provided for purposes of the study under subsection (c).

If the conference held under subsection (a) makes the finding described in this subsection, the Secretary shall establish the registry not later than six months after the completion of the conference.

(c) The Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall study the establishment and implementation of the registry under subsection (b) to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the imple-

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mentation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry is needed and appropriate. The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than two years after the date the registry is established under subsection (b).

Approved October 19, 1984.

LEGISLATIVE HISTORY—S. 2048 (H.R. 5580) (H.R. 4080):

HOUSE REPORTS: No. 98-575, Pt. 1, accompanying H.R. 4080 (Comm. on Energy and Commerce), No. 98-769 accompanying H.R. 5580 (Comm. on Energy and Commerce), and No. 98-1127 (Comm. of Conference).

SENATE REPORT No. 98-382 (Comm. on Labor and Human Resources).

CONGRESSIONAL RECORD, Vol. 130 (1984):

Apr. 11, considered and passed Senate.

June 20, 21, H.R. 5580 considered and passed House; S. 2048, amended, passed in lieu.

Oct. 3, House agreed to conference report.

Oct. 4, Senate agreed to conference report.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 20, No. 42 (1984):

Oct. 19, Presidential statement.