

National Organ Transplantation Act

Sec. 273. - Organ procurement organizations

(a) Grant authority of Secretary

- (1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b) of this section.
- (2) The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b) of this section.
- (3) The Secretary may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) of this section and other nonprofit private entities for the purpose of carrying out special projects designed to increase the number of organ donors.

(b) Qualified organizations

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

(A) is a nonprofit entity,

(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 ([42 U.S.C. 1395](#) et seq.) for the procurement of kidneys,

(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either -

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, 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 that are promulgated by the Secretary by not later than January 1, 2002, that -

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

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

(III) use multiple outcome measures as part of the certification process; and

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

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

(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,

(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

(H) 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 or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility, "histocompatibility".

(IV) 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)

(A) Not later than 90 days after November 16, 1990, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).^[1]

(B) Not later than 1 year after November 16, 1990, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) 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 [274\(b\)\(2\)\(E\)](#) of this title, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,
- (D) arrange for the appropriate tissue typing of donated organs,
- (E) have a system to allocate donated organs equitably among transplant 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 [274](#) of this title,
- (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,
- (J) evaluate annually the effectiveness of the organization in acquiring potentially available organs, and
- (K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors

Sec. 274. - Organ procurement and transplantation network

(a) Contract authority of Secretary; limitation; available appropriations

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) of this section. 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) Functions

(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 [273](#) of this title), 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,

(K) work actively to increase the supply of donated organs,

(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,

(M) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children,

(N) carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation, and

(O) provide that for purposes of this paragraph, the term "children" refers to individuals who are under the age of 18.

(c) Consideration of critical comments

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) of this section; and
- (2) the consideration by the Secretary of such critical comments

Sec. 274a. - Scientific registry

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 [274d](#) of this title an analysis of information derived from the registry

Sec. 274b. - General provisions respecting grants and contracts

(a) Application requirement

No grant may be made under this part or contract entered into under section [274](#) or [274a](#) of this title unless an application therefore 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.

(b) Special considerations and priority; planning and establishment grants

- (1) A grant for planning under section [273](#)(a)(1) of this title may be made for one year with respect to any organ procurement organization and may not exceed \$100,000.
- (2) Grants under section [273](#)(a)(2) of this title 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.
- (3) Grants or contracts under section [273](#)(a)(3) of this title may be made for not more than 3 years.

(c) Determination of grant amount; terms of payment; recordkeeping; access for purposes of audits and examination of records

(1) The Secretary shall determine the amount of a grant or contract made under section [273](#) or [274a](#) of this title. 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 [273](#) or [274a](#) of this title 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 [273](#) or [274a](#) of this title that are pertinent to such grant or contract.

(d) "Transplant center" and "organ" defined

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 [274a](#) of this title, such term includes bone marrow

Sec. 274c. - Administration

The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to -

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act ([42 U.S.C. 1395](#) et seq.),

(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, the Organ Procurement and Transplantation Network established under section [274](#) of this title, and other entities in the health care system involved in organ donations, procurement, and transplants, and

(4) provide information -

(i) to patients, their families, and their physicians about transplantation; and

(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and 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

Sec. 274d. - Report

Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and 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. 274e. - Prohibition of organ purchases

(a) Prohibition

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) Penalties

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

(c) Definitions

For purposes of subsection (a) of this section:

- (1)** The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) 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 [321](#)(b) of title [21](#)

Sec. 274f. - 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) of this section 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

Sec. 274g. - 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