

/* 42 USC 274, regarding organ transplants and bone marrow follows. 274(e) requires standards to avoid transplantation of organs carrying HIV. 274(k) also requires that bone marrow be screened for HIV. */

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). 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 371 [42 USC 273]), 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. [, and]

(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) 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); and

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

(July 1, 1944, ch 373, Title III, Part H, 372, as added Oct. 19, 1984, P. L. 98-507, Title II, 201, 98 Stat. 2342; Nov. 4, 1988, P. L. 100-607, Title IV, 403, 102 Stat. 3115; Nov. 16, 1990, P. L. 101-616, Title II, 202(a)-(c), 104 Stat. 3283.)

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 376 [42 USC 274d] an analysis of information derived from the registry.

(July 1, 1944, ch 373, Title III, Part H, 373, as added Oct. 19, 1984, P. L. 98-507, Title II, 201, 98 Stat. 2342; Nov. 4, 1988, P. L. 100-607, Title IV, 404, 102 Stat. 3116; Nov. 16, 1990, P. L. 101-616, Title I, 101(b) 104 Stat. 3282.)

274b. General provisions respecting grants and contracts

(a) Application requirement. No grant may be made under this part [42 USC 273 et seq.] or contract entered into under section 372 or 373 [42 USC 274 or 274a] 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.

(b) Special considerations and priority; planning and establishment grants. (1) A grant for planning under section 371(a)(1) [42 USC 273(a)(1)] may be made for one year with respect to any organ procurement organization and may not

exceed \$100,000.

(2) Grants under section 371(a)(2) [42 USC 273(a)(2)] 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 371(a)(3) [42 USC 273(a)(3)] may be made for not more than 3 years.

(c) Determination of grant amount; terms of payment; record-keeping; access for purposes of audits and examination of records. (1) The Secretary shall determine the amount of a grant or contract made under section 371 or 373 [42 USC 273 or 274a]. 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 [42 USC 273 or 274a] 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 [42 USC 273 or 274a] that are pertinent to such grant or contract.

(d) "Transplant center" and "organ" defined. For purposes of this part [42 USC 273 et seq.]:

(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 [42 USC 274a], such term includes bone marrow.

(July 1, 1944, ch 373, Title III, Part H, 374, as added Oct. 19, 1984, P. L. 98-507, Title II, 201, 98 Stat. 2342; Nov. 4, 1988, P. L. 100-607, Title IV, 402(b), 102 Stat. 3114; Nov. 16, 1990, P. L. 101-616, Title II, 203, 104 Stat. 3284.)

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,

(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 372 [42 USC 274], 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.

(July 1, 1944, ch 373, Title III, Part H, 375, as added Oct. 19, 1984, P. L. 98-507, Title II, 201, 98 Stat. 2342; Nov. 4, 1988, P. L. 100-607, Title IV, 405, 102 Stat. 3116; Nov. 16, 1990, P. L. 101-616, Title II, 204, 104 Stat. 3285.)

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.

(July 1, 1944, ch 373, Title III, Part H, 376, as added Oct. 19, 1984, P. L. 98-507, Title II, 201, 98 Stat. 2342; Nov. 4, 1988, P. L. 100-607, Title IV, 406, 102 Stat. 3116; Nov. 16, 1990, P. L. 101-616, Title II, 205, 104 Stat. 3285.)

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) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.

(c) Definitions. For purposes of subsection (a):

(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 201(b) of the Federal Food, Drug and Cosmetic Act [21 USC 321(b)].

(Oct. 19, 1984, P. L. 98-507, Title II, 301, 98 Stat. 2346; Nov. 4, 1988, P. L. 100-607, Title IV, 407, 102 Stat. 3116.)

274k. National Registry

(a) Establishment. The Secretary shall by contract establish

and maintain a National Bone Marrow Donor Registry (referred to in this part [42 USC 274k et seq.] as the "Registry") that meets the requirements of this section. The Registry shall be under the general supervision of the Secretary, and under the direction of a board of directors that shall include representatives of marrow donor centers, marrow transplant centers, persons with expertise in the social science, and the general public.

(b) Functions. The Registry shall:

(1) establish a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation;

(2) establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients, their families, and their physicians in the search for an unrelated marrow donor;

(3) increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors for the Registry in order to enable an individual in a minority group, to the extent practicable, to have a comparable chance of finding a suitable unrelated donor as would an individual not in a minority group;

(4) provide information to physicians, other health care professionals, and the public regarding bone marrow transplantation;

(5) recruit potential bone marrow donors;

(6) collect, analyze, and publish data concerning bone marrow donation and transplantation; and

(7) support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be marrow donors.

(c) Criteria, standards, and procedures. Not later than 180 days after the date of enactment of this part [enacted Nov. 16, 1990], the Secretary shall establish and enforce, for entities participating in the program, including the Registry, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers:

(1) quality standards and standards for tissue typing,

obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards that require the provision of information to patients, their families, and their physicians at the start of the search process concerning:

(A) the resources available through the Registry;

(B) all other marrow donor registries meeting the standards described in this paragraph; and

(C) in the case of the Registry:

(i) the comparative costs of all charges by marrow transplant centers incurred by patients prior to transplantation; and

(ii) the success rates of individual marrow transplant centers;

(5) standards that:

(A) require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Registry.

(d) Comment Procedures. The Secretary shall establish and

provide information to the public on procedures, which may include establishment of a policy advisory committee, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Registry is carrying out the duties of the Registry under subsection (b) and complying with the criteria, standards, and procedures described in subsection (c).

(e) Consultation. The Secretary shall consult with the board of directors of the Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

(f) Application. To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(g) Eligibility. Entities eligible to receive a contract under this section shall include private nonprofit entities.

(h) Records. (1) Recordkeeping. Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) Examination of records. The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(i) Penalties for disclosure. Any person who discloses the content of any record referred to in subsection (c) (5) (A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (c) (5) (B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

(j) Authorization of appropriations. There are authorized to be appropriated to carry out this section \$15,000,000 for fiscal

year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.

(July 1, 1944, ch 373, Title III, Part I, 379, as added Nov. 16, 1990, P. L. 101-616, Title I, 101(a)(2), 104 Stat. 3279.)

2741. Study by the General Accounting Office

(a) In general. The Comptroller General of the United States shall conduct a study that evaluates:

(1) the costs and benefits of the search process for an unrelated bone marrow donor among different marrow donor registries;

(2) the extent to which marrow donor registries protect donor confidentiality;

(3) the relationship between the Registry, individual marrow donor centers, and other marrow donor registries;

(4) the effectiveness and appropriateness of policies and procedures of marrow donor centers, marrow transplant centers, and marrow donor registries, including:

(A) the process of donor recruitment, including the policy of asking each donor whether the donor would want to donate more than one time;

(B) the maintenance and updating of donor files; and

(C) the policy of initially typing donors for A/B antigens only instead of initially typing for both A/B and D/R antigens;

(5) the ability of the marrow donor registries to incorporate changes in medical research and clinical practice; and

(6) the costs associated with tissue typing.

(b) Report. Not later than 1 year after the date of enactment of this part [enacted Nov. 16, 1990], the Comptroller General shall complete the study required under subsection (a) 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 describing the findings made by the study and recommendations for legislative reform.

(July 1, 1944, ch 373, Title III, Part I, 379A, as added Nov. 16, 1990, P. L. 101-616, Title I, 101(a)(2), 104 Stat. 3282.)