conducted by the Department of Health and Human Services has created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of organ donation.

''(3) The General Accounting Office [now Government Accountability Office], the Institute of Medicine, and the Harvard School of Public Health have identified substantial limitations in the organ procurement organization certification and recertification process and have recommended changes in that process.

''(4) The limitations in the recertification process include:

''(A) An exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.

''(B) A lack of due process to appeal to the Secretary of Health and Human Services for recertification on either substantive or procedural grounds.

''(5) The Secretary of Health and Human Services has the authority under section 1138(b)(1)(A)(i) of the Social Security Act (42 U.S.C. 1320b–8(b)(1)(A)(i)) to extend the period for recertification of an organ procurement organization from 2 to 4 years on the basis of its past practices in order to avoid the inappropriate disruption of the nation's organ system.

''(6) The Secretary of Health and Human Services can use the extended period described in paragraph (5) for recertification of all organ procurement organizations to—

''(A) develop improved performance measures that would reflect organ donor potential and interim outcomes, and to test these measures to ensure that they accurately measure performance differences among the organ procurement organizations; and

''(B) improve the overall certification process by incorporating process as well as outcome performance measures, and developing equitable processes for appeals.''

STUDY REGARDING IMMUNOSUPPRESSIVE DRUGS

Pub. L. 106–310, div. A, title XXI, § 2101(b), Oct. 17, 2000, 114 Stat. 1156, provided that:

''(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall provide for a study to determine the costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance cover such costs. The Secretary may carry out the study directly or through a grant to the Institute of Medicine (or other public or nonprofit private entity).

''(2) RECOMMENDATIONS REGARDING CERTAIN ISSUES.—The Secretary shall ensure that, in addition to making determinations under paragraph (1), the study under such paragraph makes recommendations regarding the following issues:

''(A) The costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans, health insurance and government programs cover such costs.

''(B) The extent of denial of organs to be released for transplant by coroners and medical examiners.

''(C) The special growth and developmental issues that children have pre- and post-organ transplantation.

''(D) Other issues that are particular to the special health and transplantation needs of children.

''(3) REPORT.—The Secretary shall ensure that, not later than December 31, 2001, the study under paragraph (1) is completed and a report describing the findings of the study is submitted to the Congress.''

STUDY ON HOSPITAL AGREEMENTS WITH ORGAN PROCUREMENT AGENCIES

Pub. L. 103–432, title I, § 155(b), Oct. 31, 1994, 108 Stat. 4439, directed Office of Technology Assessment to conduct study to determine efficacy and fairness of requiring a hospital to enter into agreement under subsec. (b)(3)(A) of this section with organ procurement agency for service area in which such hospital is located and impact of such requirement on efficacy and fairness of organ procurement and distribution, and to submit to Congress, not later than 2 years after Oct. 31, 1994, report containing findings of such study and implications of such findings with respect to policies affecting organ procurement and distribution.

TASK FORCE ON ORGAN PROCUREMENT AND TRANSPLANTATION

Pub. L. 98–507, title I, §§ 101–105, Oct. 19, 1984, 98 Stat. 2339–2342, directed Secretary of Health and Human Services, not later than 90 days after Oct. 19, 1984, to establish a Task Force on Organ Transplantation to conduct comprehensive examinations, prepare an assessment and report, and submit advice as to regulation of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation, with the final report due not later than 12 months after the Task Force is established and the Task Force to terminate 3 months thereafter.

BONE MARROW REGISTRY DEMONSTRATION AND STUDY

Section 401 of Pub. L. 98–507 directed Secretary of Health and Human Services to hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors not later than 9 months after Oct. 19, 1984, and if the conference found that it was feasible to establish a national registry of voluntary donors of bone marrow and that such a registry was likely to be effective in matching donors with recipients, the Secretary was to establish a registry of voluntary donors of bone marrow not later than six months after the completion of the conference, and further directed the Secretary, acting through the Assistant Secretary for Health, to study the establishment and implementation of the registry to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the implementation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry was needed and appropriate, and to report the results of the study to Congress not later than two years after the date the registry was established.

§ 273a. National living donor mechanisms

The Secretary may establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations by individuals who have served as living donors.

(July 1, 1944, ch. 373, title III, § 371A, as added Pub. L. 108–216, § 7, Apr. 5, 2004, 118 Stat. 589.)

§ 273b. Report on the long-term health effects of living organ donation

Not later than 1 year after December 21, 2007, and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that details the progress made towards understanding the long-term health effects of living organ donation.

(Pub. L. 110–144, § 3, Dec. 21, 2007, 121 Stat. 1814.)

CODIFICATION

Section was enacted as part of the Charlie W. Norwood Living Organ Donation Act, and not as part of the

Public Health Service Act which comprises this chapter.

§ 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, polices, 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.

(July 1, 1944, ch. 373, title III, § 372, as added Pub. L. 98–507, title II, § 201, Oct. 19, 1984, 98 Stat. 2344; amended Pub. L. 100–607, title IV, § 403, Nov. 4, 1988, 102 Stat. 3115; Pub. L. 101–616, title II, § 202(a)–(c), Nov. 16, 1990, 104 Stat. 3283, 3284; Pub. L. 106–310, div. A, title XXI, § 2101(a), Oct. 17, 2000, 114 Stat. 1156.)

PRIOR PROVISIONS

A prior section 274, act July 1, 1944, ch. 373, title III, § 372, as added July 28, 1956, ch. 772, title II, § 201, 70 Stat. 710; amended June 25, 1959, Pub. L. 86–70, § 31(b)(2)–(4), 73 Stat. 148, related to grants to Alaska for a mental health program and payment for construction of hospital facilities, prior to the general revision of this part by section 201 of Pub. L. 98–507.

Another section 372 of act July 1, 1944, added by act Aug. 3, 1956, ch. 941, § 1, 70 Stat. 960, which related to functions of National Library of Medicine, was renumbered section 382 and classified to section 276 of this title, prior to repeal by Pub. L. 99–158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2000—Subsec. (b)(2)(M) to(O). Pub. L. 106–310 added subpars. (M) to (O).