

oaths in matters pertaining to the administration of the quarantine laws and regulations of the United States.

(July 1, 1944, ch. 373, title III, §369, 58 Stat. 706.)

PART H—ORGAN TRANSPLANTS

PRIOR PROVISIONS

A prior part H related to grants to Alaska for mental health, prior to the general revision of part H by Pub. L. 98-507, title II, §201, Oct. 19, 1984, 98 Stat. 2342.

Another prior part H, entitled "National Library of Medicine", as added by act Aug. 3, 1956, ch. 907, 70 Stat. 960, was redesignated part I and classified to section 275 et seq. of this title, prior to repeal by Pub. L. 99-158.

§ 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.

(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)¹ 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;²

(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 histocompatibility³ or an individual with a doctorate degree in a biological science 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)¹ 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),¹ 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—

² So in original. The semicolon probably should be a comma.

³ So in original. Probably should be "histocompatibility".

¹ See References in Text note below.

(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.

(c) Pancreata islet cell transplantation or research

Pancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b) of this section.

(July 1, 1944, ch. 373, title III, § 371, as added Pub. L. 98-507, title II, § 201, Oct. 19, 1984, 98 Stat. 2342; amended Pub. L. 100-607, title IV, § 402(a), (c)(1), (2), (d), Nov. 4, 1988, 102 Stat. 3114, 3115; Pub. L. 101-616, title II, §§ 201(a)-(c)(1), (d), (e), 206(b), Nov. 16, 1990, 104 Stat. 3283, 3285; Pub. L. 106-505, title VII, § 701(c), Nov. 13, 2000, 114 Stat. 2347; Pub. L. 106-554, § 1(a)(1) [title II, § 219(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-29; Pub. L. 108-216, § 9, Apr. 5, 2004, 118 Stat. 590; Pub. L. 108-362, § 2, Oct. 25, 2004, 118 Stat. 1703.)

REFERENCES IN TEXT

Paragraph (2), referred to in subsec. (b)(1), meaning paragraph (2) of subsec. (b) of this section, was redesignated paragraph (3) by section 201(d)(1) of Pub. L. 101-616. See 1990 Amendment note below.

The Social Security Act, referred to in subsec. (b)(1)(C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XVIII of the Social Security Act is classified generally to subchapter XVIII (§1395 et seq.) of

chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Paragraph (1)(E), referred to in subsec. (b)(2)(A), meaning paragraph (1)(E) of subsec. (b) of this section, was redesignated paragraph (1)(F) by section 701(c)(1) of Pub. L. 106-505 and section 1(a)(1) [title II, § 219(b)(1)] of Pub. L. 106-554. See 2000 Amendment note below.

PRIOR PROVISIONS

A prior section 273, act July 1, 1944, ch. 373, title III, § 371, as added July 28, 1956, ch. 772, title II, § 201, 70 Stat. 709, authorized grants to the Territory of Alaska for an integrated mental health program, prior to repeal by Pub. L. 86-70, § 31(b)(1), June 25, 1959, 73 Stat. 148, effective July 1, 1959.

A prior section 371 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 960, was renumbered section 381 and classified to section 275 of this title, prior to repeal by Pub. L. 99-158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2004—Subsec. (a)(3). Pub. L. 108-216 struck out par. (3) which read as follows: “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.”

Subsec. (c). Pub. L. 108-362 added subsec. (c).

2000—Subsec. (b)(1)(D) to (H). Pub. L. 106-505 and Pub. L. 106-554 amended par. (1) identically, adding subpar. (D), redesignating former subpars. (D) to (G) as (E) to (H), respectively, and realigning margins of subpar. (F).

1990—Pub. L. 101-616, § 201(a), substituted “Organ procurement organizations” for “Assistance for organ procurement organizations” in section catchline.

Subsec. (a)(3). Pub. L. 101-616, § 201(b)(1), substituted “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” for “may make grants for special projects”.

Subsec. (a)(4). Pub. L. 101-616, § 201(b)(2), struck out par. (4) which set forth factors to consider in making grants.

Subsec. (b)(1)(E). Pub. L. 101-616, § 201(c)(1), amended subpar. (E) generally. Prior to amendment, subpar. (E) read as follows: “has a defined service area which is a geographical area of sufficient size such that (unless the service area comprises an entire State) the organization can reasonably expect to procure organs from not less than 50 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.”

Subsec. (b)(1)(G)(i)(III). Pub. L. 101-616, § 201(e), made technical correction to Pub. L. 100-607, § 402(c)(2). See 1988 Amendment note below.

Subsec. (b)(2), (3). Pub. L. 101-616, § 201(d), added par. (2) and redesignated former par. (2) as (3).

Subsec. (c). Pub. L. 101-616, § 206(b), struck out subsec. (c) which authorized appropriations for subsec. (a) grants for fiscal years 1988 through 1990.

1988—Subsec. (a)(2). Pub. L. 100-607, § 402(a)(1), inserted “consolidation,” after “initial operation.”

Subsec. (a)(3). Pub. L. 100-607, § 402(a)(2), added par. (3). Former par. (3) redesignated (4).

Subsec. (a)(4). Pub. L. 100-607, § 402(a)(2), redesignated former par. (3) as (4).

Subsec. (a)(4)(C). Pub. L. 100-607, § 402(a)(3), added subpar. (C).

Subsec. (b)(1)(E). Pub. L. 100-607, § 402(c)(1)(A), substituted “size such that” for “size which”, and “the organization can reasonably expect to procure organs from not less than 50 donors each year” for “will include at least fifty potential organ donors each year”.

Subsec. (b)(1)(G)(i)(III). Pub. L. 100-607, § 402(c)(2), as amended by Pub. L. 101-616, § 201(e), inserted “or an in-

dividual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility” before comma at end.

Subsec. (b)(2)(C). Pub. L. 100-607, § 402(c)(1)(B), substituted “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,” for “274(b)(2)(D) of this title.”

Subsec. (b)(2)(E). Pub. L. 100-607, § 402(c)(1)(C), substituted “organs equitably among transplant patients” for “organs among transplant centers and patients”.

Subsec. (b)(2)(K). Pub. L. 100-607, § 402(c)(1)(D), added subpar. (K).

Subsec. (c). Pub. L. 100-607, § 402(d), amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: “For grants under subsection (a) of this section 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.”

EFFECTIVE DATE OF 1990 AMENDMENT

Section 207 of title II of Pub. L. 101-616 provided that: “Except as otherwise provided in this title, the amendments made by this title [enacting sections 274f and 274g of this title, amending this section and sections 274 and 274b to 274d of this title, and repealing provisions set out as a note below] shall become effective on October 1, 1990, or on the date of the enactment of this Act [Nov. 16, 1990], whichever occurs later.”

EFFECTIVE DATE OF 1988 AMENDMENT

Section 402(c)(3) of Pub. L. 100-607, as amended by Pub. L. 101-274, Apr. 23, 1990, 104 Stat. 139, which provided that the amendment made by section 402(c)(1)(A) of Pub. L. 100-607, amending this section, was not to apply to an organ procurement organization designated under section 1320b-8(b) of this title until Jan. 1, 1992, was repealed by Pub. L. 101-616, title II, § 201(c)(2), Nov. 16, 1990, 104 Stat. 3283.

SHORT TITLE

For short title of Pub. L. 98-507, which enacted this part as the “National Organ Transplant Act”, see section 1 of Pub. L. 98-507, set out as a Short Title of 1984 Amendments note under section 201 of this title.

SEVERABILITY

Section 301 of Pub. L. 101-616 provided that: “If any provision of this Act [enacting sections 274f, 274g, 274k, and 274l of this title, amending this section and sections 274 to 274d of this title, enacting provisions set out as notes under this section and sections 274 and 274k of this title, and repealing provisions set out as a note above], amendment made by this Act, or application of the provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions or amendments to any person or circumstance shall not be affected.”

CERTIFICATION OF ORGAN PROCUREMENT ORGANIZATIONS

Pub. L. 106-505, title VII, § 701(b), Nov. 13, 2000, 114 Stat. 2346, and Pub. L. 106-554, § 1(a)(1) [title II, § 219(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A-28, provided that: “Congress makes the following findings:

“(1) Organ procurement organizations play an important role in the effort to increase organ donation in the United States.

“(2) The current process for the certification and recertification of organ procurement organizations 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 requir-

ing 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 \$7,000,000. 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,