

§ 271. Penalties for violation of quarantine laws**(a) Penalties for persons violating quarantine laws**

Any person who violates any regulation prescribed under sections 264 to 266 of this title, or any provision of section 269 of this title or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without permission of the quarantine officer in charge, shall be punished by a fine of not more than \$1,000 or by imprisonment for not more than one year, or both.

(b) Penalties for vessels violating quarantine laws

Any vessel which violates section 269 of this title, or any regulations thereunder or under section 267 of this title, or which enters within or departs from the limits of any quarantine station, ground, or anchorage in disregard of the quarantine rules and regulations or without permission of the officer in charge, shall forfeit to the United States not more than \$5,000, the amount to be determined by the court, which shall be a lien on such vessel, to be recovered by proceedings in the proper district court of the United States. In all such proceedings the United States attorney shall appear on behalf of the United States; and all such proceedings shall be conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States.

(c) Remittance or mitigation of forfeitures

With the approval of the Secretary, the Surgeon General may, upon application therefor, remit or mitigate any forfeiture provided for under subsection (b) of this section, and he shall have authority to ascertain the facts upon all such applications.

(July 1, 1944, ch. 373, title III, §368, 58 Stat. 706; June 25, 1948, ch. 646, §1, 62 Stat. 909; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

CHANGE OF NAME

Act June 25, 1948, eff. Sept. 1, 1948, substituted "United States attorney" for "United States district attorney". See section 541 of Title 28, Judiciary and Judicial Procedure, and Historical and Revision note thereunder.

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by

section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953. Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20.

§ 272. Administration of oaths by quarantine officers

Medical officers of the United States, when performing duties as quarantine officers at any port or place within the United States, are authorized to take declarations and administer 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—

¹ See References in Text note below.

- (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 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.

(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 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 (3)(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 (3), 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 Fed-

eral 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 identifying organs that are infected with human immunodeficiency virus (HIV),

- (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; Pub. L. 113-51, §2(a)(2), (3), Nov. 21, 2013, 127 Stat. 579, 580.)

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

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

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

2013—Subsec. (b)(1)(E), (F). Pub. L. 113-51, §2(a)(3)(A), (B), redesignated subpars. (F) and (G) as (E) and (F), respectively, and struck out former subpar. (E) which read as follows: “has procedures to obtain payment for non-renal organs provided to transplant centers.”

Subsec. (b)(1)(G). Pub. L. 113-51, §2(a)(3)(C), which directed the substitution of “(G) has a director” for “(H) has a director”, was executed by substituting “(G) has a board of directors” for “(H) has a board of directors” to reflect the probable intent of Congress. Former subpar. (G) redesignated (F).

Subsec. (b)(1)(G)(i)(V), (ii). Pub. L. 113-51, §2(a)(3)(D), which directed the amendment of subpar. (H) by substituting “paragraph (3)(G)” for “paragraph (2)(G)” in cl. (i)(V) and “paragraph (3)” for “paragraph (2)” in cl. (ii), was executed by making the substitutions in subpars. (G)(i)(V) and (G)(ii), respectively, to reflect the probable intent of Congress and the redesignation of subpar. (H) as (G) by Pub. L. 113-51, §2(a)(3)(C). See above.

Subsec. (b)(3)(C). Pub. L. 113-51, §2(a)(2), substituted “including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV)” for “including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome”.

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 individual 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

Pub. L. 101-616, title II, §207, Nov. 16, 1990, 104 Stat. 3286, 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

Pub. L. 100-607, title IV, §402(c)(3), Nov. 4, 1988, 102 Stat. 3115, 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 sec-

tion 1 of Pub. L. 98-507, set out as a Short Title of 1984 Amendments note under section 201 of this title.

SEVERABILITY

Pub. L. 101-616, title III, §301, Nov. 16, 1990, 104 Stat. 3286, 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 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

Pub. L. 98-507, title IV, §401, Oct. 19, 1984, 98 Stat. 3268, 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 estab-

lished 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,

(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.

(3) CLARIFICATION.—In adopting and using standards of quality under paragraph (2)(E), the Organ Procurement and Transplantation Network may adopt and use such standards with respect to organs infected with human immunodeficiency virus (in this paragraph referred to as “HIV”), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who—

(A) are infected with HIV before receiving such organ; and

(B)(i) are participating in clinical research approved by an institutional review board under the criteria, standards, and regulations described in subsections (a) and (b) of section 274f-5 of this title; or

(ii) if the Secretary has determined under section 274f-5(c) of this title that participation in such clinical research, as a requirement for such transplants, is no longer warranted, are receiving a transplant under the standards and regulations under section 274f-5(c) of this title.

(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; Pub. L. 110-426, § 2, Oct. 15, 2008, 122 Stat. 4835; Pub. L. 113-51, § 2(a)(1), Nov. 21, 2013, 127 Stat. 579.)

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

2013—Subsec. (b)(2)(E). Pub. L. 113-51, § 2(a)(1)(A), struck out “, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome” after “organs”.

Subsec. (b)(3). Pub. L. 113-51, § 2(a)(1)(B), added par. (3).

2008—Subsec. (a). Pub. L. 110-426 substituted “\$7,000,000” for “\$2,000,000”.

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

1990—Subsec. (b)(1)(A). Pub. L. 101-616, § 202(a)(1), substituted “that has an expertise in organ procurement and transplantation” for “which is not engaged in any activity unrelated to organ procurement”.

Subsec. (b)(1)(B). Pub. L. 101-616, § 202(a)(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 273 of this title), transplant centers, voluntary health associations, and the general public.”

Subsec. (b)(2)(D). Pub. L. 101-616, § 202(b)(1), inserted “nationwide” after “organizations in the” and “equitably among transplant patients” after “organs”.

Subsec. (b)(2)(F). Pub. L. 101-616, § 202(c), substituted “compatibility” for “compatability”.

Subsec. (b)(2)(K), (L). Pub. L. 101-616, § 202(b)(2)-(4), added subpars. (K) and (L).

1988—Subsec. (b)(2)(B), (C). Pub. L. 100-607, § 403(a)(1), added subpar. (B) and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (b)(2)(D). Pub. L. 100-607, § 403(a)(1), (2), redesignated former subpar. (C) as (D) and substituted “organs” for “organs which cannot be placed within the service areas of the organizations”. Former subpar. (D) redesignated (E).

Subsec. (b)(2)(E). Pub. L. 100-607, § 403(a)(1), (3), redesignated former subpar. (D) as (E) and inserted “including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,” after “organs.” Former subpar. (E) redesignated (F).

Subsec. (b)(2)(F). Pub. L. 100-607, § 403(a)(1), (4), redesignated former subpar. (E) as (F) and inserted “(and, to the extent practicable, among regions or on a national basis)” after “basis”. Former subpar. (F) redesignated (G).

Subsec. (b)(2)(G) to (I). Pub. L. 100-607, § 403(a)(1), redesignated former subpars. (F) to (H) as (G) to (I), respectively.

Subsec. (b)(2)(J). Pub. L. 100-607, § 403(a)(5), added subpar. (J).

Subsec. (c). Pub. L. 100-607, § 403(b), added subsec. (c).

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101-616, title II, § 202(d), Nov. 16, 1990, 104 Stat. 3284, provided that: “The amendments made by subsection (a) [amending this section] shall become effective on December 31, 1990.”

REPORT; LIMITATION ON AMENDMENT BY PUB. L. 110-426

Pub. L. 110-426, § 3, Oct. 15, 2008, 122 Stat. 4835, provided that:

“(a) IN GENERAL.—The Secretary of Health and Human Services shall request that the Executive Director of the Organ Procurement and Transplantation Network submit to Congress, not later than 1 year after the date of enactment of this Act [Oct. 15, 2008], a report that shall include—

“(1) the identity of transplant programs that have become inactive or have closed since the heart allocation policy change of 2006;

“(2) the distance to the next closest operational heart transplant center from such inactivated or closed programs and an evaluation of whether or not access to care has been reduced to the population previously serviced by such inactive or closed program;

“(3) the number of patients with rural zip codes that received transplants after the heart allocation policy change of 2006 as compared with the number of such patients that received such transplants prior to such heart allocation policy change;

“(4) a comparison of the number of transplants performed, the mortality rate for individuals on the transplant waiting lists, and the post-transplant survival rate nationally and by region prior to and after the heart allocation policy change of 2006; and

“(5) specifically with respect to allosensitized patients, a comparison of the number of heart transplants performed, the mortality rate for individuals on the heart transplant waiting lists, and the post heart transplant survival rate nationally and by region prior to and after the heart allocation policy change of 2006.

“(b) LIMITATION ON FUNDING.—The increase provided for in the amendment made by section 2 [amending this section] shall not apply with respect to contracts entered into under section 372(a) of the Public Health Service Act (42 U.S.C. 274(a)) after the date that is 1 year after the date of enactment of this Act [Oct. 15, 2008] if the Executive Director of the Organ Procurement and Transplantation Network fails to submit the report under subsection (a).”

§ 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.

(July 1, 1944, ch. 373, title III, § 373, as added Pub. L. 98-507, title II, § 201, Oct. 19, 1984, 98 Stat. 2345; amended Pub. L. 100-607, title IV, § 404, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101-616, title I, § 101(b), Nov. 16, 1990, 104 Stat. 3282.)

PRIOR PROVISIONS

A prior section 373 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 960, which related to a Board of Regents of National Library of Medicine, was renumbered section 383 and classified to section 277 of this title, prior to repeal by Pub. L. 99-158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Pub. L. 101-616 struck out “and bone marrow registry” after “Scientific registry” in section catchline and struck out subsec. (a) designation and subsec. (b) which directed establishment of bone marrow registry and authorized appropriations for fiscal years 1989 and 1990 for such purpose.

1988—Pub. L. 100-607 inserted “and bone marrow registry” in section catchline, designated existing text as subsec. (a), and added subsec. (b).

§ 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 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 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.

(July 1, 1944, ch. 373, title III, § 374, as added Pub. L. 98-507, title II, § 201, Oct. 19, 1984, 98 Stat. 2345; amended Pub. L. 100-607, title IV, § 402(b), Nov. 4, 1988, 102 Stat. 3114; Pub. L. 101-616, title II, § 203, Nov. 16, 1990, 104 Stat. 3284.)

PRIOR PROVISIONS

A prior section 374 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 961, which related to acceptance and administration of gifts to National Library of Medicine and to establishment of memorials to donors, was renumbered section 384 and classified to section 278 of this title, prior to repeal by Pub. L. 99-158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Subsec. (a). Pub. L. 101-616, § 203(1), substituted “No grant may be made under this part” for “No grant may be made under section 273 or 274a of this title”.

Subsec. (b). Pub. L. 101-616, § 203(2), redesignated par. (2) as (1) and substituted “section 273(a)(1)” for “section 273”, struck out former par. (1) which set forth factors in considering applications for section 273 grants, redesignated par. (3) as (2) and substituted “section 273(a)(2)” for “paragraphs (2) and (3) of section 273(a)”, and added par. (3).

Subsec. (c). Pub. L. 101-616, § 203(3), inserted “or contract” after “grant” wherever appearing and “and contracts” after “grants” wherever appearing.

1988—Subsec. (b)(3). Pub. L. 100-607 substituted “paragraphs (2) and (3) of section 273(a) of this title” for “section 273 of this title for the establishment, initial operation, or expansion of organ procurement organizations”.

§ 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.

(July 1, 1944, ch. 373, title III, § 375, as added Pub. L. 98-507, title II, § 201, Oct. 19, 1984, 98 Stat. 2346; amended Pub. L. 100-607, title IV, § 405, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101-616, title II, § 204, Nov. 16, 1990, 104 Stat. 3285.)

REFERENCES IN TEXT

The Social Security Act, referred to in par. (1), 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.

PRIOR PROVISIONS

A prior section 375 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 962, which related to definitions, was renumbered section 385 and classified to section 279 of this title, prior to repeal by Pub. L. 99-158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Pub. L. 101-616, § 204(a), struck out “, during fiscal years 1985 through 1990,” after “The Secretary shall”.

Par. (3). Pub. L. 101-616, § 204(b)(1), struck out “receiving funds under section 273 of this title” after “organ procurement organizations”.

Par. (4). Pub. L. 101-616, § 204(b)(2), amended par. (4) generally. Prior to amendment, par. (4) read as follows: “not later than April 1 of each of the years 1989 and 1990, submit to the Congress a 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.”

1988—Pub. L. 100-607, in introductory provisions, substituted “1985 through 1990” for “1985, 1986, 1987, and 1988” and, in par. (4), substituted “not later than April 1 of each of the years 1989 and 1990, submit to the Congress a report” for “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”.

§ 274d. Report

Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall pub-

lish, 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,¹ 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, § 376, as added Pub. L. 98-507, title II, § 201, Oct. 19, 1984, 98 Stat. 2346; amended Pub. L. 100-607, title IV, § 406, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101-616, title II, § 205, Nov. 16, 1990, 104 Stat. 3285.)

PRIOR PROVISIONS

A prior section 376 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, § 1, 70 Stat. 962, which related to Library facilities, was renumbered section 386 and classified to section 280 of this title, prior to repeal by Pub. L. 99-158, § 3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Pub. L. 101-616 substituted “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.” for “The Secretary shall, not later than October 1 of each year, publish”.

1988—Pub. L. 100-607 substituted “shall, not later than October 1 of each year,” for “shall annually”.

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§ 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. The preceding sentence does not apply with respect to human organ paired donation.

(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

¹ So in original. The period probably should be a comma.

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.

(4) The term “human organ paired donation” means the donation and receipt of human organs under the following circumstances:

(A) An individual (referred to in this paragraph as the “first donor”) desires to make a living donation of a human organ specifically to a particular patient (referred to in this paragraph as the “first patient”), but such donor is biologically incompatible as a donor for such patient.

(B) A second individual (referred to in this paragraph as the “second donor”) desires to make a living donation of a human organ specifically to a second particular patient (referred to in this paragraph as the “second patient”), but such donor is biologically incompatible as a donor for such patient.

(C) Subject to subparagraph (D), the first donor is biologically compatible as a donor of a human organ for the second patient, and the second donor is biologically compatible as a donor of a human organ for the first patient.

(D) If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a human organ for a patient in such group.

(E) All donors and patients in the group of donor-patient pairs (whether 2 pairs or more than 2 pairs) enter into a single agreement to donate and receive such human organs, respectively, according to such biological compatibility in the group.

(F) Other than as described in subparagraph (E), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the human organs referred to in such subparagraph.

(Pub. L. 98-507, title III, §301, Oct. 19, 1984, 98 Stat. 2346; Pub. L. 100-607, title IV, §407, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 110-144, §2, Dec. 21, 2007, 121 Stat. 1813.)

CODIFICATION

Section was enacted as part of the National Organ Transplant Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2007—Subsec. (a). Pub. L. 110-144, §2(1), inserted at end “The preceding sentence does not apply with respect to human organ paired donation.”

Subsec. (c)(4). Pub. L. 110-144, §2(2), added par. (4).

1988—Subsec. (c)(1). Pub. L. 100-607 amended par. (1) generally. Prior to amendment, par. (1) read as follows: “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.”

NO IMPACT ON SOCIAL SECURITY TRUST FUND

Pub. L. 110-144, §4, Dec. 21, 2007, 121 Stat. 1814, provided that: “Nothing in this Act [see Short Title of 2007 Amendment note set out under section 201 of this title] (or an amendment made by this Act) shall be construed to alter or amend the Social Security Act (42 U.S.C. 301 et seq.) (or any regulation promulgated under that Act).”

§ 274f. Reimbursement of travel and subsistence expenses incurred toward living organ donation

(a) In general

The Secretary may award grants to States, transplant centers, qualified organ procurement organizations under section 273 of this title, or other public or private entities for the purpose of—

(1) providing for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred to as “donating individuals”); and

(2) providing for the reimbursement of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

(b) Preference

The Secretary shall, in carrying out subsection (a) of this section, give preference to those individuals that the Secretary determines are more likely to be otherwise unable to meet such expenses.

(c) Certain circumstances

The Secretary may, in carrying out subsection (a) of this section, consider—

(1) the term “donating individuals” as including individuals who in good faith incur qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs; and

(2) the term “qualifying expenses” as including the expenses of having relatives or other individuals, not to exceed 2, accompany or assist the donating individual for purposes of subsection (a) of this section (subject to making payment for only those types of expenses that are paid for a donating individual).

(d) Relationship to payments under other programs

An award may be made under subsection (a) of this section only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such expenses—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program;

(2) by an entity that provides health services on a prepaid basis; or

(3) by the recipient of the organ.

(e) Definitions

For purposes of this section:

(1) The term “donating individuals” has the meaning indicated for such term in subsection (a)(1) of this section, subject to subsection (c)(1) of this section.

(2) The term “qualifying expenses” means the expenses authorized for purposes of subsection (a) of this section, subject to subsection (c)(2) of this section.

(f) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated \$5,000,000 for each of the fiscal years 2005 through 2009.

(July 1, 1944, ch. 373, title III, § 377, as added Pub. L. 101-616, title II, § 206(a), Nov. 16, 1990, 104 Stat. 3285; amended Pub. L. 108-216, § 3, Apr. 5, 2004, 118 Stat. 584.)

AMENDMENTS

2004—Pub. L. 108-216 amended section catchline and text generally, substituting provisions relating to reimbursement of travel and subsistence expenses incurred toward living organ donation for provisions requiring the Comptroller General to study and report on organ procurement and allocation.

§ 274f-1. Public awareness; studies and demonstrations**(a) Organ donation public awareness program**

The Secretary shall, directly or through grants or contracts, establish a public education program in cooperation with existing national public awareness campaigns to increase awareness about organ donation and the need to provide for an adequate rate of such donations.

(b) Studies and demonstrations

The Secretary may make peer-reviewed grants to, or enter into peer-reviewed contracts with, public and nonprofit private entities for the purpose of carrying out studies and demonstration projects to increase organ donation and recovery rates, including living donation.

(c) Grants to States**(1) In general**

The Secretary may make grants to States for the purpose of assisting States in carrying out organ donor awareness, public education, and outreach activities and programs designed to increase the number of organ donors within the State, including living donors.

(2) Eligibility

To be eligible to receive a grant under this subsection, a State shall—

(A) submit an application to the Department in the form prescribed;

(B) establish yearly benchmarks for improvement in organ donation rates in the State; and

(C) report to the Secretary on an annual basis a description and assessment of the State’s use of funds received under this subsection, accompanied by an assessment of initiatives for potential replication in other States.

(3) Use of funds

Funds received under this subsection may be used by the State, or in partnership with other

public agencies or private sector institutions, for education and awareness efforts, information dissemination, activities pertaining to the State donor registry, and other innovative donation specific initiatives, including living donation.

(d) Educational activities

The Secretary, in coordination with the Organ Procurement and Transplantation Network and other appropriate organizations, shall support the development and dissemination of educational materials to inform health care professionals and other appropriate professionals in issues surrounding organ, tissue, and eye donation including evidence-based proven methods to approach patients and their families, cultural sensitivities, and other relevant issues.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated \$15,000,000 for fiscal year 2005, and such sums as may be necessary for each of the fiscal years 2006 through 2009. Such authorization of appropriations is in addition to any other authorizations of appropriations that are available for such purpose.

(July 1, 1944, ch. 373, title III, § 377A, as added Pub. L. 108-216, § 4, Apr. 5, 2004, 118 Stat. 585.)

§ 274f-2. Grants regarding hospital organ donation coordinators**(a) Authority****(1) In general**

The Secretary may award grants to qualified organ procurement organizations and hospitals under section 273 of this title to establish programs coordinating organ donation activities of eligible hospitals and qualified organ procurement organizations under section 273 of this title. Such activities shall be coordinated to increase the rate of organ donations for such hospitals.

(2) Eligible hospital

For purposes of this section, the term “eligible hospital” means a hospital that performs significant trauma care, or a hospital or consortium of hospitals that serves a population base of not fewer than 200,000 individuals.

(b) Administration of coordination program

A condition for the receipt of a grant under subsection (a) of this section is that the applicant involved agree that the program under such subsection will be carried out jointly—

(1) by representatives from the eligible hospital and the qualified organ procurement organization with respect to which the grant is made; and

(2) by such other entities as the representatives referred to in paragraph (1) may designate.

(c) Requirements

Each entity receiving a grant under subsection (a) of this section shall—

(1) establish joint organ procurement organization and hospital designated leadership responsibility and accountability for the project;

(2) develop mutually agreed upon overall project performance goals and outcome measures, including interim outcome targets; and

(3) collaboratively design and implement an appropriate data collection process to provide ongoing feedback to hospital and organ procurement organization leadership on project progress and results.

(d) Rule of construction

Nothing in this section shall be construed to interfere with regulations in force on April 5, 2004.

(e) Evaluations

Within 3 years after the award of grants under this section, the Secretary shall ensure an evaluation of programs carried out pursuant to subsection (a) of this section in order to determine the extent to which the programs have increased the rate of organ donation for the eligible hospitals involved.

(f) Matching requirement

The Secretary may not award a grant to a qualifying organ donation entity under this section unless such entity agrees that, with respect to costs to be incurred by the entity in carrying out activities for which the grant was awarded, the entity shall contribute (directly or through donations from public or private entities) non-Federal contributions in cash or in kind, in an amount equal to not less than 30 percent of the amount of the grant awarded to such entity.

(g) Funding

For the purpose of carrying out this section, there are authorized to be appropriated \$3,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

(July 1, 1944, ch. 373, title III, §377B, as added Pub. L. 108-216, §4, Apr. 5, 2004, 118 Stat. 586.)

§ 274f-3. Studies relating to organ donation and the recovery, preservation, and transportation of organs

(a) Development of supportive information

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall develop scientific evidence in support of efforts to increase organ donation and improve the recovery, preservation, and transportation of organs.

(b) Activities

In carrying out subsection (a) of this section, the Secretary shall—

(1) conduct or support evaluation research to determine whether interventions, technologies, or other activities improve the effectiveness, efficiency, or quality of existing organ donation practice;

(2) undertake or support periodic reviews of the scientific literature to assist efforts of professional societies to ensure that the clinical practice guidelines that they develop reflect the latest scientific findings;

(3) ensure that scientific evidence of the research and other activities undertaken under this section is readily accessible by the organ procurement workforce; and

(4) work in coordination with the appropriate professional societies as well as the Organ Procurement and Transplantation Network and other organ procurement and transplantation organizations to develop evidence and promote the adoption of such proven practices.

(c) Research and dissemination

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, as appropriate, shall provide support for research and dissemination of findings, to—

(1) develop a uniform clinical vocabulary for organ recovery;

(2) apply information technology and telecommunications to support the clinical operations of organ procurement organizations;

(3) enhance the skill levels of the organ procurement workforce in undertaking quality improvement activities; and

(4) assess specific organ recovery, preservation, and transportation technologies.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated \$2,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

(July 1, 1944, ch. 373, title III, §377C, as added Pub. L. 108-216, §5, Apr. 5, 2004, 118 Stat. 587.)

§ 274f-4. Report relating to organ donation and the recovery, preservation, and transportation of organs

(a) In general

Not later than December 31, 2005, and every 2 years thereafter, the Secretary shall report to the appropriate committees of Congress on the activities of the Department carried out pursuant to this part, including an evaluation describing the extent to which the activities have affected the rate of organ donation and recovery.

(b) Requirements

To the extent practicable, each report submitted under subsection (a) of this section shall—

(1) evaluate the effectiveness of activities, identify effective activities, and disseminate such findings with respect to organ donation and recovery;

(2) assess organ donation and recovery activities that are recently completed, ongoing, or planned; and

(3) evaluate progress on the implementation of the plan required under subsection (c)(5) of this section.

(c) Initial report requirements

The initial report under subsection (a) of this section shall include the following:

(1) An evaluation of the organ donation practices of organ procurement organizations, States, other countries, and other appropriate organizations including an examination across all populations, including those with low organ donation rates, of—

(A) existing barriers to organ donation; and

(B) the most effective donation and recovery practices.

(2) An evaluation of living donation practices and procedures. Such evaluation shall include an assessment of issues relating to informed consent and the health risks associated with living donation (including possible reduction of long-term effects).

(3) An evaluation of—

(A) federally supported or conducted organ donation efforts and policies, as well as federally supported or conducted basic, clinical, and health services research (including research on preservation techniques and organ rejection and compatibility); and

(B) the coordination of such efforts across relevant agencies within the Department and throughout the Federal Government.

(4) An evaluation of the costs and benefits of State donor registries, including the status of existing State donor registries, the effect of State donor registries on organ donation rates, issues relating to consent, and recommendations regarding improving the effectiveness of State donor registries in increasing overall organ donation rates.

(5) A plan to improve federally supported or conducted organ donation and recovery activities, including, when appropriate, the establishment of baselines and benchmarks to measure overall outcomes of these programs. Such plan shall provide for the ongoing coordination of federally supported or conducted organ donation and research activities.

(July 1, 1944, ch. 373, title III, §377D, as added Pub. L. 108-216, §6, Apr. 5, 2004, 118 Stat. 588.)

§ 274f-5. Criteria, standards, and regulations with respect to organs infected with HIV

(a) In general

Not later than 2 years after November 21, 2013, the Secretary shall develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with human immunodeficiency virus (in this section referred to as “HIV”) into individuals who are infected with HIV before receiving such organ.

(b) Corresponding changes to standards and regulations applicable to research

Not later than 2 years after November 21, 2013, to the extent determined by the Secretary to be necessary to allow the conduct of research in accordance with the criteria developed under subsection (a)—

(1) the Organ Procurement and Transplantation Network shall revise the standards of quality adopted under section 274(b)(2)(E) of this title; and

(2) the Secretary shall revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(c) Revision of standards and regulations generally

Not later than 4 years after November 21, 2013, and annually thereafter, the Secretary,¹ shall—

(1) review the results of scientific research in conjunction with the Organ Procurement

and Transplantation Network to determine whether the results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV;

(2) if the Secretary determines under paragraph (1) that such results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV, direct the Organ Procurement and Transplantation Network to revise such standards, consistent with section 274 of this title and in a way that ensures the changes will not reduce the safety of organ transplantation; and

(3) in conjunction with any revision of such standards under paragraph (2), revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(July 1, 1944, ch. 373, title III, §377E, as added Pub. L. 113-51, §2(b), Nov. 21, 2013, 127 Stat. 580.)

§ 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.

(July 1, 1944, ch. 373, title III, §378, as added Pub. L. 101-616, title II, §206(a), Nov. 16, 1990, 104 Stat. 3285; amended Pub. L. 105-196, §4(1), July 16, 1998, 112 Stat. 636.)

AMENDMENTS

1998—Pub. L. 105-196 made technical amendment relating to placement of section within part H of this subchapter.

PART H-1—Stephanie Tubbs Jones Gift of Life Medal

CODIFICATION

Part was enacted as part of the Stephanie Tubbs Jones Gift of Life Medal Act of 2008, and not as part of the Public Health Service Act which comprises this chapter.

§ 274i. Eligibility requirements for Stephanie Tubbs Jones Gift of Life Medal

(a) In general

Subject to the provisions of this section and the availability of funds under this part, any organ donor, or the family of any organ donor, shall be eligible for a Stephanie Tubbs Jones Gift of Life Medal (hereafter in this part referred to as a “medal”).

(b) Documentation

The Secretary of Health and Human Services shall direct the entity operating the Organ Procurement and Transplantation Network to—

(1) establish an application procedure requiring the relevant organ procurement organization through which an individual or family of

¹ So in original. The comma probably should not appear.