

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, required the Secretary of Health and Human Services to provide for a study to determine the costs of immunosuppressive drugs provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance covered such costs, and related issues, and to submit the report to Congress by Dec. 31, 2001.

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.)

Editorial Notes

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) In general**

The Secretary shall provide for the continued operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The Secretary may

award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.

(b) Composition

(1) IN GENERAL.—The Organ Procurement and Transplantation Network shall—

(A) be operated through awards to public or private entities made by the Secretary that are distinct from the awards made to support the organization tasked with supporting the board of directors described in subparagraph (B); 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,

(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); 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; Pub. L. 118–14, § 2, Sept. 22, 2023, 137 Stat. 69.)

Editorial Notes

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

2023—Subsec. (a). Pub. L. 118-14, §2(1), inserted heading, substituted “The Secretary shall” for “The Secretary shall by contract”, “continued” for “establishment and”, and “The Secretary may award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.” for “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.”

Subsec. (b). Pub. L. 118-14, §2(2), inserted subsec. and par. (1) headings and, in par. (1), substituted “The Organ Procurement and Transplantation Network shall—” and subpar. (A) for “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”.

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 “compatibility”.

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).

Statutory Notes and Related Subsidiaries

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;