

Public Law 101-616
101st Congress

An Act

To amend the Public Health Service Act to revise and extend the program establishing the National Bone Marrow Donor Registry, and for other purposes.

Nov. 16, 1990

[S. 2946]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Transplant
Amendments
Act of 1990.
42 USC 201
note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Transplant Amendments Act of 1990".

SEC. 2. TABLE OF CONTENTS.

Sec. 1. Short title.

Sec. 2. Table of contents.

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**TITLE I—NATIONAL BONE MARROW
DONOR REGISTRY**

SEC. 101. ESTABLISHMENT OF A NATIONAL BONE MARROW DONOR REGISTRY.

(a) **REGISTRY.**—Title III of the Public Health Service Act (42 U.S.C. 301 et seq.) is amended—

(1) by redesignating parts I, J, and K as parts J, K, and L, respectively; and

(2) by inserting after section 377 (as added by section 207 of this Act) the following new part:

42 USC 275 et
seq., 280b et seq.,
280c et seq.

**“PART I—NATIONAL BONE MARROW DONOR
REGISTRY**

“SEC. 379. NATIONAL REGISTRY.

42 USC 274k.

“(a) **ESTABLISHMENT.**—The Secretary shall by contract establish and maintain a National Bone Marrow Donor Registry (referred to in this part as the ‘Registry’) that meets the requirements of this

Government
contracts.

section. The Registry shall be under the general supervision of the Secretary, and under the direction of a board of directors that shall include representatives of marrow donor centers, marrow transplant centers, persons with expertise in the social science, and the general public.

“(b) FUNCTIONS.—The Registry shall—

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

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

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

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

“(5) recruit potential bone marrow donors;

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

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

“(c) CRITERIA, STANDARDS, AND PROCEDURES.—Not later than 180 days after the date of enactment of this part, the Secretary shall establish and enforce, for entities participating in the program, including the Registry, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

“(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

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

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

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

“(A) the resources available through the Registry;

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

“(C) in the case of the Registry—

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

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

“(5) standards that—

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

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

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

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

Public information.

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

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

Regulations.

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

“(h) RECORDS.—

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

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

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

“(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$15,000,000 for fiscal year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.

42 USC 274l.

“SEC. 379A. STUDY BY THE GENERAL ACCOUNTING OFFICE.

“(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study that evaluates—

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

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

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

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

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

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

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

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

“(6) the costs associated with tissue typing.

“(b) REPORT.—Not later than 1 year after the date of enactment of this part, the Comptroller General shall complete the study required under subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the findings made by the study and recommendations for legislative reform.”.

(b) CONFORMING AMENDMENT.—Section 373 of the Act (42 U.S.C. 274a) is amended—

(1) in the section heading, by striking “and Bone Marrow Registry”;

(2) by striking “(a)”; and

(3) by striking out subsection (b).

42 USC 274k
note.**SEC. 102. SAVINGS PROVISIONS.**

(a) IN GENERAL.—This title, and the amendments made by this title, shall not affect any legal document, including any order, regulation, grant, or contract, in effect on the date of enactment of this Act, or any administrative proceeding or lawsuit pending on the date, that relates to the bone marrow registry established under section 373(b) of the Public Health Service Act (as it existed before the amendment made by section 101(b) of this Act).

(b) CONTINUED EFFECT.—A legal document described in subsection (a) or an order issued in a lawsuit described in subsection (a) shall continue in effect until modified, terminated, or revoked.

(c) PROCEEDINGS.—In any administrative proceeding or lawsuit described in subsection (a), parties shall take appeals, and officials shall hold proceedings and render judgments, in the same manner and with the same effect as if this title had not been enacted.

TITLE II—ORGAN TRANSPLANTS

SEC. 201. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS.

(a) **SECTION HEADING.**—Section 371 of the Public Health Service Act (42 U.S.C. 273) is amended in the section heading by striking “assistance for”.

(b) **AUTHORITY REGARDING CERTAIN GRANTS.**—

(1) **SPECIAL PROJECTS.**—Section 371(a)(3) of the Act (42 U.S.C. 273(a)(3)) is amended by striking “may make grants for special projects” and inserting the following: “may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) and other nonprofit private entities for the purpose of carrying out special projects”.

(2) **CONSIDERATIONS IN MAKING CERTAIN GRANTS.**—Section 371(a) of the Act (42 U.S.C. 273(a)) is amended by striking paragraph (4).

(c) **SERVICE AREA OF QUALIFIED ORGAN PROCUREMENT ORGANIZATIONS.**—

(1) **IN GENERAL.**—Subparagraph (E) of section 371(b)(1) of the Act (42 U.S.C. 273(b)(1)(E)) is amended to read as follows:

“(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.”

(2) **CONFORMING AMENDMENT.**—Section 402(c)(3) of the Health Omnibus Programs Extension of 1988 (Public Law 100-607; 42 U.S.C. 273 note) is repealed.

(d) **EFFECTIVENESS REGARDING NUMBER OF ORGANS PROCURED.**—Section 371(b) of the Public Health Service Act (42 U.S.C. 273(b)) is amended—

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by inserting after paragraph (1) the following new paragraph:

“(2)(A) Not later than 90 days after the date of the enactment of this paragraph, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).

“(B) Not later than 1 year after the date of enactment of this paragraph, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).”

(e) **TECHNICAL CORRECTION REGARDING PUBLIC LAW 100-607.**—Section 402(c)(2) of the Health Omnibus Programs Extension of 1988 (Public Law 100-607; 102 Stat. 3115) is amended by inserting “at the end” after “the comma”.

Federal
Register,
publication.

42 USC 273.

SEC. 202. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(a) **MINIMUM QUALIFICATIONS OF CONTRACTOR.**—Section 372(b)(1) of the Public Health Service Act (42 U.S.C. 274(b)(1)) is amended—

(1) in subparagraph (A), by striking “which is not engaged in any activity unrelated to organ procurement” and inserting “that has an expertise in organ procurement and transplantation”; and

(2) in subparagraph (B), to read as follows:

“(B) have a board of directors—

“(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 371), transplant centers, voluntary health associations, and the general public; and

Establishment.

“(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.”

(b) RESPONSIBILITIES OF NETWORK.—Section 372(b)(2) of the Act (42 U.S.C. 274(b)(2)) is amended—

(1) in subparagraph (D)—

(A) by inserting “nationwide” after “organizations in the”; and

(B) by inserting “equitably among transplant patients” after “organs”;

(2) by striking “and” at the end of subparagraph (I);

(3) by striking the period at the end of subparagraph (J) and inserting “, and”;

(4) by adding at the end the following new subparagraphs:

“(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.”

Reports.

(c) TECHNICAL CORRECTION.—Section 372(b)(2)(F) of the Act (42 U.S.C. 274(b)(2)(F)) is amended by striking “compatibility” and inserting “compatibility”.

42 USC 274
note.

(d) EFFECTIVE DATE.—The amendments made by subsection (a) shall become effective on December 31, 1990.

SEC. 203. GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS.

Section 374 of the Public Health Service Act (42 U.S.C. 274b) is amended—

(1) in subsection (a), by striking “No grant” and all that follows through “373” the first place that the term appears and inserting the following: “No grant may be made under this part”;

(2) in subsection (b)—

(A) by striking paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively;

(B) by striking “section 371” in paragraph (1) (as so redesignated) and inserting “section 371(a)(1)”;

(C) by striking “paragraphs (2) and (3) of section 371(a)” in the first sentence of paragraph (2) (as so redesignated), and inserting “section 371(a)(2)”;

(D) by adding at the end the following new paragraph: “(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years.”; and

(3) in subsection (c)—

(A) by inserting “or contract” after “grant” in the first sentence of paragraph (1);

(B) by inserting “and contracts” after “grants” each place the term appears in the second sentence of paragraph (1); and

(C) by inserting “or contract” after “grant” each place the term appears in subparagraphs (A) and (B) of paragraph (2).

SEC. 204. ADMINISTRATION.

(a) **IDENTIFIABLE ADMINISTRATIVE UNIT.**—Section 375 of the Public Health Service Act (42 U.S.C. 274c) is amended in the matter preceding paragraph (1) by striking “, during fiscal years 1985 through 1990,”.

(b) **STRIKING OF EXPIRED REQUIREMENT REGARDING CERTAIN REPORTS.**—Section 375 of the Act (42 U.S.C. 274c) is amended—

(1) in paragraph (3), by striking “receiving funds under section 371”; and

(2) in paragraph (4), to read as follows:

“(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.”.

SEC. 205. REPORT.

Section 376 of the Public Health Service Act (42 U.S.C. 274d) is amended in the first sentence, by striking “The Secretary” and all that follows through “publish” and inserting “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.”.

SEC. 206. STUDY BY GENERAL ACCOUNTING OFFICE AND AUTHORIZATION OF APPROPRIATIONS.

(a) **IN GENERAL.**—Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by adding at the end the following new sections:

“SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.

42 USC 274f.

“(a) **IN GENERAL.**—The Comptroller General of the United States shall conduct a study for the purpose of determining—

“(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;

“(2) the problems encountered in the procurement and allocation; and

“(3) the effect of State required-request laws.

“(b) **REPORT.**—Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

“SEC. 378. AUTHORIZATION OF APPROPRIATIONS.

42 USC 274g.

“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.”.

(b) **CONFORMING AMENDMENT.**—Section 371 of the Public Health Service Act (42 U.S.C. 273) is amended by striking subsection (c).

42 USC 273
note.

SEC. 207. EFFECTIVE DATE.

Except as otherwise provided in this title, the amendments made by this title shall become effective on October 1, 1990, or on the date of the enactment of this Act, whichever occurs later.

TITLE III—SEVERABILITY

42 USC 273
note.

SEC. 301. SEVERABILITY.

If any provision of this Act, 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.

Approved November 16, 1990.

LEGISLATIVE HISTORY—S. 2946:

SENATE REPORTS: No. 101-530 (Comm. on Labor and Human Resources).
CONGRESSIONAL RECORD, Vol. 136 (1990):

Oct. 25, considered and passed Senate.

Oct. 26, considered and passed House.

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