Public Law 105–196
105th Congress

An Act

To amend the Public Health Service Act to revise and extend the bone marrow donor program, and for other purposes.

July 16, 1998

[H.R. 2202]

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

National Bone Marrow Registry Reauthorization Act of 1998.
42 USC 201 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Bone Marrow Registry Reauthorization Act of 1998".

SEC. 2. REAUTHORIZATION.

(a) ESTABLISHMENT OF REGISTRY.—Section 379(a) of the Public Health Service Act (42 U.S.C. 274k(a)) is amended—

(1) by striking "(referred to in this part as the 'Registry') that meets" and inserting "(referred to in this part as the 'Registry') that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow, and that meets";

(2) by striking "under the direction of a board of directors that shall include representatives of" and all that follows and inserting the following: "under the direction of a board of directors meeting the following requirements:

"(1) Each member of the board shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that such limitations shall not apply to the Chair of the board (or the Chair-elect) or to the member of the board who most recently served as the Chair.

"(2) A member of the board may continue to serve after the expiration of the term of such member until a successor is appointed.

"(3) In order to ensure the continuity of the board, the board shall be appointed so that each year the terms of approximately one-third of the members of the board expire.

"(4) The membership of the board shall include representatives of marrow donor centers and marrow transplant centers; recipients of a bone marrow transplant; persons who require or have required such a transplant; family members of such a recipient or family members of a patient who has requested the assistance of the Registry in searching for an unrelated donor of bone marrow; persons with expertise in the social sciences; and members of the general public; and in addition nonvoting representatives from the Naval Medical Research and Development Command and from the Division of Organ

Transplantation of the Health Resources and Services Administration.".

(b) PROGRAM FOR UNRELATED MARROW TRANSPLANTS.—

(1) IN GENERAL.—Section 379(b) of the Public Health Service Act (42 U.S.C. 274k(b)) is amended by redesignating paragraph (7) as paragraph (8), and by striking paragraphs (2) through (6) and inserting the following:

"(2) carry out a program for the recruitment of bone marrow donors in accordance with subsection (c), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Registry;

"(3) carry out informational and educational activities in accordance with subsection (c);

"(4) annually update information to account for changes in the status of individuals as potential donors of bone marrow;

"(5) provide for a system of patient advocacy through the office established under subsection (d);

"(6) provide case management services for any potential donor of bone marrow to whom the Registry has provided a notice that the potential donor may be suitably matched to a particular patient (which services shall be provided through a mechanism other than the system of patient advocacy under subsection (d)), and conduct surveys of donors and potential donors to determine the extent of satisfaction with such services and to identify ways in which the services can be improved;

"(7) with respect to searches for unrelated donors of bone marrow that are conducted through the system under paragraph (1), collect and analyze and publish data on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached; the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances; and comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers; and".

42 USC 274k note.

(2) REPORT OF INSPECTOR GENERAL; PLAN REGARDING RELATIONSHIP BETWEEN REGISTRY AND DONOR CENTERS.—The Secretary of Health and Human Services shall ensure that, not later than 1 year after the date of the enactment of this Act, the National Bone Marrow Donor Registry (under section 379 of the Public Health Service Act) develops, evaluates, and implements a plan to effectuate efficiencies in the relationship between such Registry and donor centers. The plan shall incorporate, to the extent practicable, the findings and recommendations made in the inspection conducted by the Office of the Inspector General (Department of Health and Human Services) as of January 1997 and known as the Bone Marrow Program Inspection.

(c) PROGRAM FOR INFORMATION AND EDUCATION.—Section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended by striking subsection (j), by redesignating subsections (c) through (i) as subsections (e) through (k), respectively, and by inserting after subsection (b) the following subsection:

"(c) RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

"(1) RECRUITMENT; PRIORITIES.—The Registry shall carry out a program for the recruitment of bone marrow donors.

Such program shall identify populations that are underrepresented among potential donors enrolled with the Registry. In the case of populations that are identified under the preceding sentence:

"(A) The Registry shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

"(B) The Registry shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

"(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

"(A) IN GENERAL.—In carrying out the program under paragraph (1), the Registry shall carry out informational and educational activities for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Registry potential donors. Such information and educational activities shall include the following:

"(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

"(ii) Educating and providing information to individuals who are willing to serve as potential donors, including providing updates.

"(iii) Training individuals in requesting individuals to serve as potential donors.

"(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Registry shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

"(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding the availability, as a potential treatment option, of receiving a transplant of bone marrow from an unrelated donor.".

(d) PATIENT ADVOCACY AND CASE MANAGEMENT.—Section 379 of the Public Health Service Act (42 U.S.C. 274k), as amended by subsection (c) of this section, is amended by inserting after subsection (c) the following subsection:

"(d) PATIENT ADVOCACY; CASE MANAGEMENT.— Establishment.

"(1) IN GENERAL.—The Registry shall establish and maintain an office of patient advocacy (in this subsection referred to as the 'Office').

"(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

"(A) The Office shall be headed by a director.

"(B) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Registry is conducting, or has been requested to conduct, a search for an unrelated donor of bone marrow.

"(C) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under subsection (b)(1) to conduct an ongoing search for a donor.

"(D) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the search needs of the patient involved are being met, including with respect to the following:

"(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding donors who are suitability matched to the patient, and other information regarding the progress being made in the search.

"(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

"(iii) Identifying and resolving problems in the search, to the extent practicable.

"(E) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the Registry, donor centers, transplant centers, and other entities participating in the Registry program are complying with standards issued under subsection (e)(4) for the system for patient advocacy under this subsection.

"(F) The Office shall ensure that the following data are made available to patients:

"(i) The resources available through the Registry.

"(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

"(iii) A list of donor registries, transplant centers, and other entities that meet the applicable standards, criteria, and procedures under subsection (e).

"(iv) The posttransplant outcomes for individual transplant centers.

"(v) Such other information as the Registry determines to be appropriate.

"(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved.

"(3) CASE MANAGEMENT.—

"(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

"(i) individualized case assessment; and

"(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

“(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office may, on behalf of patients who have completed the search for an unrelated donor, provide information and education on the process of receiving a transplant of bone marrow, including the posttransplant process.”.

(e) CRITERIA, STANDARDS, AND PROCEDURES.—Section 379(e) of the Public Health Service Act (42 U.S.C. 274k), as redesignated by subsection (c) of this section, is amended by striking paragraph (4) and inserting the following:

“(4) standards for the system for patient advocacy operated under subsection (d), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;”.

(f) REPORT.—Section 379 of the Public Health Service Act, as amended by subsection (c) of this section, is amended by adding at the end the following subsection:

“(l) ANNUAL REPORT REGARDING PRETRANSPLANT COSTS.—The Registry shall annually submit to the Secretary the data collected under subsection (b)(7) on comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers. The data shall be submitted to the Secretary through inclusion in the annual report required in section 379A(c).”.

(g) CONFORMING AMENDMENTS.—Section 379 of the Public Health Service Act, as amended by subsection (c) of this section, is amended—

(1) in subsection (f), by striking “subsection (c)” and inserting “subsection (e)”; and

(2) in subsection (k), by striking “subsection (c)(5)(A)” and inserting “subsection (e)(5)(A)” and by striking “subsection (c)(5)(B)” and inserting “subsection (e)(5)(B)”.

SEC. 3. RECIPIENT REGISTRY.

Part I of title III of the Public Health Service Act (42 U.S.C. 274k et seq.) is amended by striking section 379A and inserting the following:

“SEC. 379A. BONE MARROW SCIENTIFIC REGISTRY.

42 USC 274*l*.

“(a) ESTABLISHMENT OF RECIPIENT REGISTRY.—The Secretary, acting through the Registry under section 379 (in this section referred to as the ‘Registry’), shall establish and maintain a scientific registry of information relating to patients who have been recipients of a transplant of bone marrow from a biologically unrelated donor.

“(b) INFORMATION.—The scientific registry under subsection (a) shall include information with respect to patients described in subsection (a), transplant procedures, and such other information as the Secretary determines to be appropriate to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of bone marrow from biologically unrelated donors.

“(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Registry shall annually submit to the Secretary a report concerning patient outcomes with respect to each transplant center. Each such report shall use data collected and maintained by the scientific registry under subsection (a). Each such report shall in addition include the data required in section 379(l) (relating to pretransplant costs).".

SEC. 4. AUTHORIZATION OF APPROPRIATIONS.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended—

42 USC 274g.

(1) by transferring section 378 from the current placement of the section and inserting the section after section 377; and

(2) in part I, by inserting after section 379A the following section:

42 USC 274m.

"SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

"For the purpose of carrying out this part, there are authorized to be appropriated $18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003.".

42 USC 274k note.

SEC. 5. STUDY BY GENERAL ACCOUNTING OFFICE.

(a) IN GENERAL.—During the period indicated pursuant to subsection (b), the Comptroller General of the United States shall conduct a study of the National Bone Marrow Donor Registry under section 379 of the Public Health Service Act for purposes of making determinations of the following:

(1) The extent to which, relative to the effective date of this Act, such Registry has increased the representation of racial and ethnic minority groups (including persons of mixed ancestry) among potential donors of bone marrow who are enrolled with the Registry, and whether the extent of increase results in a level of representation that meets the standard established in subsection (c)(1)(A) of such section 379 (as added by section 2(c) of this Act).

(2) The extent to which patients in need of a transplant of bone marrow from a biologically unrelated donor, and the physicians of such patients, have been utilizing the Registry in the search for such a donor.

(3) The number of such patients for whom the Registry began a preliminary search but for whom the full search process was not completed, and the reasons underlying such circumstances.

(4) The extent to which the plan required in section 2(b)(2) of this Act (relating to the relationship between the Registry and donor centers) has been implemented.

(5) The extent to which the Registry, donor centers, donor registries, collection centers, transplant centers, and other appropriate entities have been complying with the standards, criteria, and procedures under subsection (e) of such section 379 (as redesignated by section 2(c) of this Act).

Deadline.

(b) REPORT.—A report describing the findings of the study under subsection (a) shall be submitted to the Congress not later than October 1, 2001. The report may not be submitted before January 1, 2001.

Deadline.
42 USC 274k note.

SEC. 6. COMPLIANCE WITH NEW REQUIREMENTS FOR OFFICE OF PATIENT ADVOCACY.

With respect to requirements for the office of patient advocacy under section 379(d) of the Public Health Service Act, the Secretary of Health and Human Services shall ensure that, not later than 180 days after the effective date of this Act, such office is in compliance with all requirements (established pursuant to the amendment made by section 2(d)) that are additional to the requirements that under section 379 of such Act were in effect with respect to patient advocacy on the day before the date of the enactment of this Act.

SEC. 7. EFFECTIVE DATE.

42 USC 274k note.

This Act takes effect October 1, 1998, or upon the date of the enactment of this Act, whichever occurs later.

Approved July 16, 1998.

LEGISLATIVE HISTORY—H.R. 2202:

HOUSE REPORTS: No. 105–538 (Comm. on Commerce).
CONGRESSIONAL RECORD, Vol. 144 (1998):
May 19, considered and passed House.
June 24, considered and passed Senate.

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