

105TH CONGRESS
2^D SESSION

H. R. 2202

IN THE SENATE OF THE UNITED STATES

MAY 20, 1998

Received; read twice and referred to the Committee on Labor and Human
Resources

AN ACT

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “National Bone Marrow
3 Registry Reauthorization Act of 1998”.

4 **SEC. 2. REAUTHORIZATION.**

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

8 (1) by striking “(referred to in this part as the
9 ‘Registry’) that meets” and inserting “(referred to
10 in this part as the ‘Registry’) that has the purpose
11 of increasing the number of transplants for recipi-
12 ents suitably matched to biologically unrelated do-
13 nors of bone marrow, and that meets”;

14 (2) by striking “under the direction of a board
15 of directors that shall include representatives of”
16 and all that follows and inserting the following:
17 “under the direction of a board of directors meeting
18 the following requirements:

19 “(1) Each member of the board shall serve for
20 a term of two years, and each such member may
21 serve as many as three consecutive two-year terms,
22 except that such limitations shall not apply to the
23 Chair of the board (or the Chair-elect) or to the
24 member of the board who most recently served as
25 the Chair.

1 “(2) A member of the board may continue to
2 serve after the expiration of the term of such mem-
3 ber until a successor is appointed.

4 “(3) In order to ensure the continuity of the
5 board, the board shall be appointed so that each
6 year the terms of approximately $\frac{1}{3}$ of the members
7 of the board expire.

8 “(4) The membership of the board shall include
9 representatives of marrow donor centers and marrow
10 transplant centers; recipients of a bone marrow
11 transplant; persons who require or have required
12 such a transplant; family members of such a recipi-
13 ent or family members of a patient who has re-
14 quested the assistance of the Registry in searching
15 for an unrelated donor of bone marrow; persons with
16 expertise in the social sciences; and members of the
17 general public; and in addition nonvoting representa-
18 tives from the Naval Medical Research and Develop-
19 ment Command and from the Division of Organ
20 Transplantation of the Health Resources and Serv-
21 ices Administration.”.

22 (b) PROGRAM FOR UNRELATED MARROW TRANS-
23 PLANTS.—

24 (1) IN GENERAL.—Section 379(b) of the Public
25 Health Service Act (42 U.S.C. 274k(b)) is amended

1 by redesignating paragraph (7) as paragraph (8),
2 and by striking paragraphs (2) through (6) and in-
3 serting the following:

4 “(2) carry out a program for the recruitment of
5 bone marrow donors in accordance with subsection
6 (c), including with respect to increasing the rep-
7 resentation of racial and ethnic minority groups (in-
8 cluding persons of mixed ancestry) in the enrollment
9 of the Registry;

10 “(3) carry out informational and educational
11 activities in accordance with subsection (c);

12 “(4) annually update information to account for
13 changes in the status of individuals as potential do-
14 nors of bone marrow;

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

17 “(6) provide case management services for any
18 potential donor of bone marrow to whom the Reg-
19 istry has provided a notice that the potential donor
20 may be suitably matched to a particular patient
21 (which services shall be provided through a mecha-
22 nism other than the system of patient advocacy
23 under subsection (d)), and conduct surveys of donors
24 and potential donors to determine the extent of sat-

1 isfaction with such services and to identify ways in
2 which the services can be improved;

3 “(7) with respect to searches for unrelated do-
4 nors of bone marrow that are conducted through the
5 system under paragraph (1), collect and analyze and
6 publish data on the number and percentage of pa-
7 tients at each of the various stages of the search
8 process, including data regarding the furthest stage
9 reached; the number and percentage of patients who
10 are unable to complete the search process, and the
11 reasons underlying such circumstances; and com-
12 parisons of transplant centers regarding search and
13 other costs that prior to transplantation are charged
14 to patients by transplant centers; and”.

15 (2) REPORT OF INSPECTOR GENERAL; PLAN
16 REGARDING RELATIONSHIP BETWEEN REGISTRY
17 AND DONOR CENTERS.—The Secretary of Health
18 and Human Services shall ensure that, not later
19 than one year after the date of the enactment of this
20 Act, the National Bone Marrow Donor Registry
21 (under section 379 of the Public Health Service Act)
22 develops, evaluates, and implements a plan to effec-
23 tuate efficiencies in the relationship between such
24 Registry and donor centers. The plan shall incor-
25 porate, to the extent practicable, the findings and

1 recommendations made in the inspection conducted
2 by the Office of the Inspector General (Department
3 of Health and Human Services) as of January 1997
4 and known as the Bone Marrow Program Inspec-
5 tion.

6 (c) PROGRAM FOR INFORMATION AND EDUCATION.—
7 Section 379 of the Public Health Service Act (42 U.S.C.
8 274k) is amended by striking subsection (j), by redesignig-
9 nating subsections (c) through (i) as subsections (e)
10 through (k), respectively, and by inserting after subsection
11 (b) the following subsection:

12 “(c) RECRUITMENT; PRIORITIES; INFORMATION AND
13 EDUCATION.—

14 “(1) RECRUITMENT; PRIORITIES.—The Reg-
15 istry shall carry out a program for the recruitment
16 of bone marrow donors. Such program shall identify
17 populations that are underrepresented among poten-
18 tial donors enrolled with the Registry. In the case of
19 populations that are identified under the preceding
20 sentence:

21 “(A) The Registry shall give priority to
22 carrying out activities under this part to in-
23 crease representation for such populations in
24 order to enable a member of such a population,
25 to the extent practicable, to have a probability

1 of finding a suitable unrelated donor that is
2 comparable to the probability that an individual
3 who is not a member of an underrepresented
4 population would have.

5 “(B) The Registry shall consider racial
6 and ethnic minority groups (including persons
7 of mixed ancestry) to be populations that have
8 been identified for purposes of this paragraph,
9 and shall carry out subparagraph (A) with re-
10 spect to such populations.

11 “(2) INFORMATION AND EDUCATION REGARD-
12 ING RECRUITMENT; TESTING AND ENROLLMENT.—

13 “(A) IN GENERAL.—In carrying out the
14 program under paragraph (1), the Registry
15 shall carry out informational and educational
16 activities for purposes of recruiting individuals
17 to serve as donors of bone marrow, and shall
18 test and enroll with the Registry potential do-
19 nors. Such information and educational activi-
20 ties shall include the following:

21 “(i) Making information available to
22 the general public, including information
23 describing the needs of patients with re-
24 spect to donors of bone marrow.

1 “(ii) Educating and providing infor-
2 mation to individuals who are willing to
3 serve as potential donors, including provid-
4 ing updates.

5 “(iii) Training individuals in request-
6 ing individuals to serve as potential donors.

7 “(B) PRIORITIES.—In carrying out infor-
8 mational and educational activities under sub-
9 paragraph (A), the Registry shall give priority
10 to recruiting individuals to serve as donors of
11 bone marrow for populations that are identified
12 under paragraph (1).

13 “(3) TRANSPLANTATION AS TREATMENT OP-
14 TION.—In addition to activities regarding recruit-
15 ment, the program under paragraph (1) shall pro-
16 vide information to physicians, other health care
17 professionals, and the public regarding the availabil-
18 ity, as a potential treatment option, of receiving a
19 transplant of bone marrow from an unrelated
20 donor.”.

21 (d) PATIENT ADVOCACY AND CASE MANAGEMENT.—
22 Section 379 of the Public Health Service Act (42 U.S.C.
23 274k), as amended by subsection (c) of this section, is
24 amended by inserting after subsection (c) the following
25 subsection:

1 “(d) PATIENT ADVOCACY; CASE MANAGEMENT.—

2 “(1) IN GENERAL.—The Registry shall estab-
3 lish and maintain an office of patient advocacy (in
4 this subsection referred to as the ‘Office’).

5 “(2) GENERAL FUNCTIONS.—The Office shall
6 meet the following requirements:

7 “(A) The Office shall be headed by a direc-
8 tor.

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

15 “(C) In the case of such a patient, the Of-
16 fice shall serve as an advocate for the patient
17 by directly providing to the patient (or family
18 members, physicians, or other individuals acting
19 on behalf of the patient) individualized services
20 with respect to efficiently utilizing the system
21 under subsection (b)(1) to conduct an ongoing
22 search for a donor.

23 “(D) In carrying out subparagraph (C),
24 the Office shall monitor the system under sub-
25 section (b)(1) to determine whether the search

1 needs of the patient involved are being met, in-
2 cluding with respect to the following:

3 “(i) Periodically providing to the pa-
4 tient (or an individual acting on behalf of
5 the patient) information regarding donors
6 who are suitability matched to the patient,
7 and other information regarding the
8 progress being made in the search.

9 “(ii) Informing the patient (or such
10 other individual) if the search has been in-
11 terrupted or discontinued.

12 “(iii) Identifying and resolving prob-
13 lems in the search, to the extent prac-
14 ticable.

15 “(E) In carrying out subparagraph (C),
16 the Office shall monitor the system under sub-
17 section (b)(1) to determine whether the Reg-
18 istry, donor centers, transplant centers, and
19 other entities participating in the Registry pro-
20 gram are complying with standards issued
21 under subsection (e)(4) for the system for pa-
22 tient advocacy under this subsection.

23 “(F) The Office shall ensure that the fol-
24 lowing data are made available to patients:

1 “(i) The resources available through
2 the Registry.

3 “(ii) A comparison of transplant cen-
4 ters regarding search and other costs that
5 prior to transplantation are charged to pa-
6 tients by transplant centers.

7 “(iii) A list of donor registries, trans-
8 plant centers, and other entities that meet
9 the applicable standards, criteria, and pro-
10 cedures under subsection (e).

11 “(iv) The posttransplant outcomes for
12 individual transplant centers.

13 “(v) Such other information as the
14 Registry determines to be appropriate.

15 “(G) The Office shall conduct surveys of
16 patients (or family members, physicians, or
17 other individuals acting on behalf of patients)
18 to determine the extent of satisfaction with the
19 system for patient advocacy under this sub-
20 section, and to identify ways in which the sys-
21 tem can be improved.

22 “(3) CASE MANAGEMENT.—

23 “(A) IN GENERAL.—In serving as an advo-
24 cate for a patient under paragraph (2), the Of-
25 fice shall provide individualized case manage-

1 ment services directly to the patient (or family
2 members, physicians, or other individuals acting
3 on behalf of the patient), including—

4 “(i) individualized case assessment;
5 and

6 “(ii) the functions described in para-
7 graph (2)(D) (relating to progress in the
8 search process).

9 “(B) POSTSEARCH FUNCTIONS.—In addi-
10 tion to the case management services described
11 in paragraph (1) for patients, the Office may,
12 on behalf of patients who have completed the
13 search for an unrelated donor, provide informa-
14 tion and education on the process of receiving
15 a transplant of bone marrow, including the
16 posttransplant process.”.

17 (e) CRITERIA, STANDARDS, AND PROCEDURES.—Sec-
18 tion 379(e) of the Public Health Service Act (42 U.S.C.
19 274k), as redesignated by subsection (c) of this section,
20 is amended by striking paragraph (4) and inserting the
21 following:

22 “(4) standards for the system for patient advo-
23 cacy operated under subsection (d), including stand-
24 ards requiring the provision of appropriate informa-
25 tion (at the start of the search process and through-

1 out the process) to patients and their families and
2 physicians;”.

3 (f) REPORT.—Section 379 of the Public Health Serv-
4 ice Act, as amended by subsection (c) of this section, is
5 amended by adding at the end the following subsection:

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

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

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

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

1 **SEC. 3. RECIPIENT REGISTRY.**

2 Part I of title III of the Public Health Service Act
3 (42 U.S.C. 274k et seq.) is amended by striking section
4 379A and inserting the following:

5 **“SEC. 379A. BONE MARROW SCIENTIFIC REGISTRY.**

6 “(a) ESTABLISHMENT OF RECIPIENT REGISTRY.—
7 The Secretary, acting through the Registry under section
8 379 (in this section referred to as the ‘Registry’), shall
9 establish and maintain a scientific registry of information
10 relating to patients who have been recipients of a trans-
11 plant of bone marrow from a biologically unrelated donor.

12 “(b) INFORMATION.—The scientific registry under
13 subsection (a) shall include information with respect to pa-
14 tients described in subsection (a), transplant procedures,
15 and such other information as the Secretary determines
16 to be appropriate to conduct an ongoing evaluation of the
17 scientific and clinical status of transplantation involving
18 recipients of bone marrow from biologically unrelated do-
19 nors.

20 “(c) ANNUAL REPORT ON PATIENT OUTCOMES.—
21 The Registry shall annually submit to the Secretary a re-
22 port concerning patient outcomes with respect to each
23 transplant center. Each such report shall use data col-
24 lected and maintained by the scientific registry under sub-
25 section (a). Each such report shall in addition include the

1 data required in section 379(l) (relating to pretransplant
2 costs).”.

3 **SEC. 4. AUTHORIZATION OF APPROPRIATIONS.**

4 Title III of the Public Health Service Act (42 U.S.C.
5 241 et seq.) is amended—

6 (1) by transferring section 378 from the cur-
7 rent placement of the section and inserting the sec-
8 tion after section 377; and

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

11 **“SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.**

12 “For the purpose of carrying out this part, there are
13 authorized to be appropriated \$18,000,000 for fiscal year
14 1999, and such sums as may be necessary for each of the
15 fiscal years 2000 through 2003.”.

16 **SEC. 5. STUDY BY GENERAL ACCOUNTING OFFICE.**

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

23 (1) The extent to which, relative to the effective
24 date of this Act, such Registry has increased the
25 representation of racial and ethnic minority groups

1 (including persons of mixed ancestry) among poten-
2 tial donors of bone marrow who are enrolled with
3 the Registry, and whether the extent of increase re-
4 sults in a level of representation that meets the
5 standard established in subsection (c)(1)(A) of such
6 section 379 (as added by section 2(c) of this Act).

7 (2) The extent to which patients in need of a
8 transplant of bone marrow from a biologically unre-
9 lated donor, and the physicians of such patients,
10 have been utilizing the Registry in the search for
11 such a donor.

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

16 (4) The extent to which the plan required in
17 section 2(b)(2) of this Act (relating to the relation-
18 ship between the Registry and donor centers) has
19 been implemented.

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

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

5 **SEC. 6. COMPLIANCE WITH NEW REQUIREMENTS FOR OF-**
6 **FICE OF PATIENT ADVOCACY.**

7 With respect to requirements for the office of patient
8 advocacy under section 379(d) of the Public Health Serv-
9 ice Act, the Secretary of Health and Human Services shall
10 ensure that, not later than 180 days after the effective
11 date of this Act, such office is in compliance with all re-
12 quirements (established pursuant to the amendment made
13 by section 2(d)) that are additional to the requirements
14 that under section 379 of such Act were in effect with
15 respect to patient advocacy on the day before the date of
16 the enactment of this Act.

17 **SEC. 7. EFFECTIVE DATE.**

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

Passed the House of Representatives May 19, 1998.

Attest:

ROBIN H. CARLE,

Clerk.