

103^D CONGRESS
1ST SESSION

H. R. 2659

To amend the Public Health Service Act to revise and extend programs relating to the transplantation of organs and of bone marrow.

IN THE HOUSE OF REPRESENTATIVES

JULY 15, 1993

Mr. WAXMAN (for himself, Mr. HALL of Texas, Mr. ROWLAND, Mr. TOWNS, Mr. UPTON, Mr. KLUG, and Mr. FRANKS of Connecticut) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to revise and extend programs relating to the transplantation of organs and of bone marrow.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Organ and Bone Mar-
5 row Transplantation Amendments of 1993”.

6 **SEC. 2. ORGAN PROCUREMENT ORGANIZATIONS.**

7 (a) IN GENERAL.—Section 371(a) of the Public
8 Health Service Act (42 U.S.C. 273(a)) is amended—

9 (1) by striking paragraphs (2) and (3); and

1 (2) by inserting after paragraph (1) the follow-
2 ing paragraph:

3 “(2)(A) The Secretary may make grants to, and enter
4 into contracts with, qualified organ procurement organiza-
5 tions described in subsection (b) and other public or non-
6 profit private entities for the purpose of—

7 “(i) planning and conducting programs to pro-
8 vide information and education to the public on the
9 need for organ donations; and

10 “(ii) training individuals in requesting such do-
11 nations.

12 “(B) In making awards of grants and contracts
13 under subparagraph (A), the Secretary shall give priority
14 to carrying out the purpose described in such subpara-
15 graph with respect to minority populations.”.

16 (b) REQUIREMENTS REGARDING QUALIFIED ORGAN
17 PROCUREMENT ORGANIZATIONS.—Section 371(b) of the
18 Public Health Service Act (42 U.S.C. 273(b)) is amend-
19 ed—

20 (1) in paragraph (1)—

21 (A) in the matter preceding subparagraph
22 (A), by striking “organization for which grants
23 may be made under subsection (a) is” and in-
24 serting “organization described in this sub-
25 section is”;

1 (B) in subparagraph (E), by moving the
2 subparagraph 2 ems to the left; and

3 (C) in subparagraph (G)—

4 (i) in the matter preceding clause (i),
5 by striking “has a board of directors or an
6 advisory board which” and inserting the
7 following: “has a board of directors (or an
8 advisory board, in the case of a hospital-
9 based organization) which”; and

10 (ii) in clause (i)(II), by striking
11 “members” and all that follows and insert-
12 ing the following: “both individuals who
13 have received a transplant of an organ,
14 and individuals who are part of the family
15 of an individual who has donated an organ,
16 which individuals shall constitute not less
17 than $\frac{1}{3}$ of the membership of the board
18 and which members shall, to the extent
19 practicable, be residents of the service area
20 involved,”; and

21 (2) in paragraph (3)—

22 (A) in subparagraph (A), by striking “have
23 effective agreements” and all that follows and
24 inserting the following: “with respect to each
25 hospital or other entity in its service area that

1 has facilities for organ donations, have an effective
2 agreement with the entity under which the
3 entity identifies potential organ donors and notifies
4 the organ procurement organization,”;

5 (B) in subparagraph (E), by inserting before
6 the comma at the end the following: “,
7 which system shall allocate each type of organ
8 on the basis of a single list, maintained exclusively
9 by the organ procurement organization,
10 of individuals who have been medically referred
11 to a transplant center in the service area of the
12 organization in order to receive a transplant of
13 the type of organ with respect to which the list
14 is maintained, and who are citizens or permanent
15 resident aliens of the United States”;

16 (C) in subparagraph (H), by striking “participate”
17 and all that follows and inserting the
18 following: “be a member of, and abide by the
19 rules and requirements of, the Organ Procurement
20 and Transplantation Network established
21 under section 372,”.

22 **SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION**
23 **NETWORK.**

24 Section 372(b) of the Public Health Service Act (42
25 U.S.C. 274(b)) is amended—

1 (1) in paragraph (1)—

2 (A) in subparagraph (A), by striking
3 “and” after the comma at the end; and

4 (B) by striking subparagraph (B) and in-
5 serting the following subparagraphs:

6 “(B) have a board of directors composed of not
7 more than 21 members, whose membership in-
8 cludes—

9 “(i) representatives of organ procurement
10 organizations, transplant centers, and voluntary
11 health associations; and

12 “(ii) both individuals who have received a
13 transplant of an organ, and individuals who are
14 part of the family of an individual who has do-
15 nated an organ, which individuals shall con-
16 stitute not less than $\frac{1}{3}$ of the membership of
17 the board; and

18 “(C) establish, through such board of directors,
19 an executive committee and other committees, the
20 chairs of which shall be selected to ensure continuity
21 of leadership for the board.”; and

22 (2) in paragraph (2)—

23 (A) by striking “shall—” in the matter
24 preceding subparagraph (A) and all that follows

1 through the end of clause (i) of such subpara-
2 graph and inserting the following: “shall—

3 “(A) establish (in one location or through re-
4 gional centers)—

5 “(i) with respect to each type of organ—

6 “(I) a national list of individuals who
7 have been medically referred to receive a
8 transplant of the type of organ with re-
9 spect to which the list is maintained and
10 who are citizens or permanent resident
11 aliens of the United States (which list shall
12 include the names of all individuals in-
13 cluded on lists in effect under section
14 371(b)(3)(E)), and

15 “(II) a national list of individuals who
16 have been so referred and who are in the
17 United States but are not such citizens or
18 such aliens, and”]; and

19 (B)(i) in subparagraph (J), by striking
20 “and” after the comma at the end;

21 (ii) in subparagraph (K), by striking the
22 period at the end and inserting a comma;

23 (iii) in subparagraph (L), by striking the
24 period at the end and inserting a comma; and

1 (iv) by adding at the end the following sub-
2 paragraphs:

3 “(M) establish the condition that, with respect
4 to the type of organ involved, the list under
5 subclause (II) of subparagraph (A)(i) may be consid-
6 ered in allocating an organ only if no individual on
7 the list under subclause (I) of such subparagraph is
8 a medically appropriate recipient for the organ,

9 “(N) submit to the Secretary for review and ap-
10 proval any change in the amount of fees imposed by
11 the Network for the registration of individuals on
12 the lists maintained under subparagraph (A)(i),

13 “(O) make available to the Secretary such in-
14 formation, books, and records regarding the Net-
15 work as the Secretary may require, and

16 “(P) meet such criteria regarding compliance
17 with this part as the Secretary may establish.”.

18 **SEC. 4. NATIONAL BONE MARROW DONOR REGISTRY.**

19 (a) IN GENERAL.—

20 (1) TRANSFER OF PROGRAM.—Section 379(a)
21 of the Public Health Service Act (42 U.S.C.
22 274k(a)) is amended in the first sentence by insert-
23 ing after “Secretary” the following: “, acting
24 through the Administrator of the Health Resources
25 and Services Administration,”.

1 (2) TRANSITIONAL AND SAVINGS PROVISIONS.—

2 (A) With respect to amounts made avail-
3 able under appropriations Acts for the purpose
4 of carrying out the program transferred pursu-
5 ant to paragraph (1) from the National Insti-
6 tutes of Health, the transfer of the program
7 may not be construed as affecting the availabil-
8 ity of such amounts for such purpose.

9 (B) The Secretary shall ensure that, for
10 fiscal 1994, the number of employees of the De-
11 partment of Health and Human Services who
12 are engaged in carrying out the program trans-
13 ferred by paragraph (1) is not less than the
14 number of employees who were so engaged on
15 June 28, 1993.

16 (b) PATIENT ADVOCACY; RECRUITMENT OF DO-
17 NORS.—Section 379 of the Public Health Service Act (42
18 U.S.C. 274k) is amended—

19 (1) in subsection (b)—

20 (A) in paragraph (2), by striking “estab-
21 lish” and all that follows and inserting the fol-
22 lowing: “establish a program for patient advo-
23 cacy in accordance with subsection (j);” and

24 (B) in paragraph (5), by striking “recruit”
25 and all that follows and inserting the following:

1 “establish a program for the recruitment of
2 bone marrow donors in accordance with sub-
3 section (k);”;

4 (2) by striking subsection (j); and

5 (3) by inserting after subsection (i) the follow-
6 ing subsections:

7 “(j) PATIENT ADVOCACY.—For purposes of sub-
8 section (b)(2), a program for patient advocacy is estab-
9 lished in accordance with this subsection if—

10 “(1) the program is headed by a director;

11 “(2) with respect to the procurement of bone
12 marrow, the program provides that the Director is
13 to serve as an advocate on behalf of—

14 “(A) individuals who are registered with
15 the Registry to become a recipient of a trans-
16 plant from a biologically unrelated donor;

17 “(B) the families of such individuals; and

18 “(C) the physicians involved;

19 “(3) the program provides case management
20 services for such individuals, families, and physi-
21 cians; and

22 “(4) meets such other criteria as the Secretary
23 may establish.

24 “(k) RECRUITMENT OF DONORS.—For purposes of
25 subsection (b)(5), a program for the recruitment of bone

1 marrow donors is established in accordance with this sub-
2 section if—

3 “(1) in the case of an individual who is enrolled
4 with the Registry, the program provides for annual
5 (or more frequent) informational mailings to each
6 such individual, which mailings concern the status of
7 the activities of the Registry;

8 “(2) the program provides for the training of
9 counselors to meet individually with individuals who
10 are so enrolled and who, pursuant to the Registry,
11 have been requested to undergo supplemental testing
12 pursuant to a search for bone marrow for a particu-
13 lar patient;

14 “(3) in the case of an individual described in
15 paragraph (2), provide to the individual a general
16 description of the medical condition of the patient
17 involved and an assessment of the possibility that
18 the individual is a medically appropriate donor for
19 the patient;

20 “(4) with respect to each meeting that, pursu-
21 ant to the Registry, is held with an individual de-
22 scribed in paragraph (2), the program provides for
23 the provision to the individual at each such meeting
24 of information regarding the possibility that, if it is
25 determined that it is medically inappropriate for the

1 individual to be a donor for the patient involved, a
2 sibling of the individual may nevertheless be a medi-
3 cally appropriate donor for the patient; and

4 “(5) meets such other criteria as the Secretary
5 may establish.”.

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

7 (a) IN GENERAL.—Section 379A(a) of the Public
8 Health Service Act (42 U.S.C. 274/(a)) is amended by
9 striking “conduct” in the matter preceding paragraph (1)
10 and all that follows and inserting the following: “conduct
11 a study for the purpose of—

12 “(1) assessing the extent to which the program
13 carried out under section 379 maintains the con-
14 fidentiality of the identity of individuals who are en-
15 rolled with the Registry;

16 “(2) assessing the extent to which such individ-
17 uals cooperate with the Registry when the Registry
18 requests the individuals to undergo supplemental
19 testing regarding the donation of bone marrow;

20 “(3) assessing, in the case of such individuals
21 who have been determined to be medically appro-
22 priate donors of bone marrow for the patients in-
23 volved, the extent to which such individuals are will-
24 ing to make a donation of bone marrow;

1 “(4) assessing the extent to which activities car-
2 ried out pursuant to section 379(k) provide informa-
3 tion to the individuals involved that is sufficient for
4 the individuals to make informed decisions regarding
5 the donation of bone marrow;

6 “(5) assessing the extent to which the case
7 management services provided under section
8 379(j)(3) are effective in assisting patients in receiv-
9 ing the transplants involved; and

10 “(6) developing recommendations on improving
11 the program of the Registry, including proposals to
12 increase the number of transplants with successful
13 outcomes while maintaining the confidentiality of the
14 identity of the individuals authorizing the donations
15 of bone marrow.”.

16 (b) DATE CERTAIN FOR SUBMISSION OF REPORT.—
17 Section 379A(b) of the Public Health Service Act (42
18 U.S.C. 274/(b)) is amended by striking “1 year” and all
19 that follows through “this part” and inserting the follow-
20 ing: “2 years after the date of the enactment of the Organ
21 and Bone Marrow Transplantation Amendments of
22 1993”.

1 **SEC. 6. TRANSFER OF PROGRAMS; MISCELLANEOUS CON-**
2 **FORMING AMENDMENTS.**

3 (a) IN GENERAL.—The Public Health Service Act
4 (42 U.S.C. 201 et seq.), as amended by the preceding pro-
5 visions of this Act, is amended—

6 (1) by striking title XVIII;

7 (2)(A) by transferring sections 371 through
8 377 from the current placement of such sections;

9 (B) by redesignating such sections as sections
10 1801 through 1807, respectively;

11 (C) by inserting such sections, in the appro-
12 priate sequence, after title XVII; and

13 (D) by inserting before section 1801 (as so re-
14 designated) the following:

15 “TITLE XVIII—TRANSPLANTATION OF ORGANS
16 AND OF BONE MARROW

17 “PART A—ORGAN TRANSPLANTATION”;

18 (3)(A) by striking section 378;

19 (B) by transferring sections 379 and 379A
20 from the current placement of such sections;

21 (C) by redesignating such sections as sections
22 1811 and 1813, respectively;

23 (D) by inserting such sections, in the appro-
24 priate sequence, at the end of title XVIII (as so des-
25 ignated); and

1 (E) by inserting before section 1811 (as so re-
2 designated) the following:

3 “PART B—NATIONAL BONE MARROW DONOR
4 REGISTRY”; and

5 (4) in title III (as amended by section
6 2008(i)(2)(B) of Public Law 103–43)—

7 (A) by striking the part designations and
8 headings for each of parts H and I; and

9 (B) by redesignating parts J through M as
10 parts H through K, respectively.

11 (b) CROSS-REFERENCES; OTHER CONFORMING
12 AMENDMENTS.—Title XVIII of the Public Health Service
13 Act, as added by subsection (a) of this section, is amend-
14 ed—

15 (1) in section 1801(b)(3)—

16 (A) in subparagraph (C), by striking “sec-
17 tion 372(b)(2)(E)” and inserting “section
18 1802(b)(2)(E)”; and

19 (B) in subparagraph (H), by striking “sec-
20 tion 372” and inserting “section 1802”;

21 (2) in section 1802(b)(2)(A)(i)(I), by striking
22 “section 371(b)(3)(E)” and inserting “section
23 1801(b)(3)(E)”;

24 (3) in section 1803, by striking “section 376”
25 and inserting “section 1806”;

1 (4) in section 1804—

2 (A) in subsection (a), by striking “section
3 372 or 373” and inserting “section 1802 or
4 1803”;

5 (B) in subsection (b)—

6 (i) in paragraph (1), by striking “sec-
7 tion 371(a)(1)” and inserting “section
8 1801(a)(1)”;

9 (ii) by striking paragraph (2);

10 (iii) by redesignating paragraph (3) as
11 paragraph (2); and

12 (iv) in paragraph (2) (as so redesign-
13 ated), by striking “section 371(a)(3)”
14 and inserting “section 1801(a)(2)”;

15 (C) in subsection (c), by striking “section
16 371 or 373” each place such term appears and
17 inserting “section 1801 or 1803”; and

18 (D) in subsection (d)—

19 (i) in paragraph (2), by striking “sec-
20 tion 373” and inserting “section 1803”;
21 and

22 (ii) by adding at the end the following
23 paragraph:

24 “(3) The term ‘citizens or permanent resident
25 aliens of the United States’ means individuals who

1 are citizens or nationals of the United States, or
2 who are aliens lawfully admitted for permanent resi-
3 dence in the United States (or otherwise perma-
4 nently residing in the United States under color of
5 law).”;

6 (5) in section 1805(3), by striking “section
7 372” and inserting “section 1802”;

8 (6) in section 1811, by striking “**SEC.**” and all
9 that follows through “The Secretary” in the first
10 sentence in subsection (a) and inserting the follow-
11 ing:

12 “NATIONAL REGISTRY

13 “SEC. 1811. (a) ESTABLISHMENT.—The Secretary”;
14 and

15 (7) in section 1813—

16 (A) by striking “**SEC.**” and all that follows
17 through “The Comptroller General” in sub-
18 section (a) and inserting the following:

19 “STUDY BY GENERAL ACCOUNTING OFFICE

20 “SEC. 1813. (a) IN GENERAL.—The Comptroller
21 General”; and

22 (B) in subsection (a)—

23 (i) in paragraph (1), by striking “sec-
24 tion 379” and inserting “section 1811”;

1 (ii) in paragraph (4), by striking “sec-
2 tion 379(k)” and inserting “section
3 1811(k)”;

4 (iii) in paragraph (5), by striking
5 “section 379(j)(3)” and inserting “section
6 1811(j)(3)”.

7 **SEC. 7. INFORMATION, EDUCATION, AND TRAINING RE-**
8 **GARDING TRANSPLANTATION OF BONE MAR-**
9 **ROW.**

10 Part B of title XVIII of the Public Health Service
11 Act, as added by section 6(a) of this Act, is amended by
12 inserting after section 1811 the following section:

13 “INFORMATION, EDUCATION, AND TRAINING

14 “SEC. 1812. (a) IN GENERAL.—The Secretary may
15 make grants to, and enter into contracts with, public or
16 nonprofit private entities for the purpose of—

17 “(1) planning and conducting programs to pro-
18 vide information and education to the public on the
19 need for donations of bone marrow; and

20 “(2) training individuals in requesting such do-
21 nations.

22 “(b) PRIORITIES IN MAKING GRANTS.—In making
23 awards of grants and contracts under subsection (a), the
24 Secretary shall give priority to carrying out the purpose
25 described in such subsection with respect to minority pop-
26 ulations.”.

1 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS FOR NEW**
2 **TITLE XVIII.**

3 Title XVIII of the Public Health Service Act, as
4 added by section 6(a) of this Act, is amended by adding
5 at the end the following part:

6 "PART C—GENERAL PROVISIONS
7 "AUTHORIZATION OF APPROPRIATIONS

8 "SEC. 1821. For the purpose of carrying out this title
9 (other than section 1801(a)(1)), there are authorized to
10 be appropriated \$20,000,000 for fiscal year 1994, and
11 such sums as may be necessary for each of the fiscal years
12 1995 and 1996."

13 **SEC. 9. STUDY REGARDING SYSTEM FOR ALLOCATION OF**
14 **ORGANS.**

15 (a) IN GENERAL.—The Secretary of Health and
16 Human Services (in this section referred to as the "Sec-
17 retary") shall conduct a study for the purpose of determin-
18 ing the feasibility, fairness, and enforceability of allocating
19 organs in the United States based solely upon the clinical
20 need of the patient involved and the viability of the organ
21 involved, with no consideration given to the geographic
22 area in which the transplant is to be performed or the
23 geographic area in which the donation of the organ is
24 made.

25 (b) REPORT.—Not later than 1 year after the date
26 of the enactment of this Act, the Secretary shall submit

1 to the Committee on Energy and Commerce of the House
2 of Representatives, and to the Committee on Labor and
3 Human Resources of the Senate, a report describing the
4 findings made in the study required in subsection (a).

5 **SEC. 10. ISSUANCE OF REGULATIONS.**

6 (a) ORGAN PROCUREMENT AND TRANSPLANTATION
7 NETWORK.—

8 (1) IN GENERAL.—

9 (A) Not later than the expiration of the
10 90-day period beginning on the date of the en-
11 actment of this Act, the Secretary of Health
12 and Human Services (in this section referred to
13 as the “Secretary”) shall issue a proposed rule
14 to establish regulations for criteria under part
15 A of title XVIII of the Public Health Service
16 Act (as added by section 6(a) of this Act).

17 (B) Not later than the expiration of the 1-
18 year period beginning on the date of the enact-
19 ment of this Act, the Secretary shall issue a
20 final rule to establish the regulations described
21 in subparagraph (A).

22 (2) CONSIDERATION OF CERTAIN BYLAWS AND
23 POLICIES.—In developing regulations under para-
24 graph (1), the Secretary shall consider the bylaws
25 and policies of the United Network for Organ Shar-

1 ing (established by contract under section 1802 of
2 the Public Health Service Act, as redesignated by
3 section 6(a) of this Act), as contained in the docu-
4 ment entitled “Bylaws and Policies of the United
5 Network for Organ Sharing”.

6 (3) FAILURE TO ISSUE REGULATIONS BY DATE
7 CERTAIN.—If the Secretary fails to issue a final rule
8 under subparagraph (B) of paragraph (1) before the
9 expiration of the period specified in such subpara-
10 graph—

11 (A) the proposed rule issued under sub-
12 paragraph (A) of such paragraph is upon such
13 expiration deemed to be the final rule under
14 subparagraph (B) of such paragraph (and shall
15 remain in effect until the Secretary issues a
16 final rule under such subparagraph); or

17 (B) if no such proposed rule is issued be-
18 fore such expiration, the bylaws and policies
19 specified in paragraph (2) and in effect upon
20 such expiration are deemed to be the final rule
21 under paragraph (1)(B) (and shall remain in
22 effect until the Secretary issues a final rule
23 under such paragraph).

24 (b) NATIONAL BONE MARROW DONOR REGISTRY.—

25 (1) IN GENERAL.—

1 (A) Not later than the expiration of the
2 90-day period beginning on the date of the en-
3 actment of this Act, the Secretary shall issue a
4 proposed rule to establish regulations for stand-
5 ards, criteria, and procedures under part B of
6 title XVIII of the Public Health Service Act (as
7 added by section 6(a) of this Act).

8 (B) Not later than the expiration of the 1-
9 year period beginning the date of the enactment
10 of this Act, the Secretary shall issue a final rule
11 to establish the regulations described in sub-
12 paragraph (A).

13 (2) CONSIDERATION OF CERTAIN BYLAWS AND
14 POLICIES.—In developing regulations under para-
15 graph (1), the Secretary shall consider the bylaws
16 and policies of the entity that operates the National
17 Bone Marrow Donor Registry pursuant to a contract
18 under section 1811 of the Public Health Service Act
19 (as redesignated by section 6(a) of this Act).

20 (3) FAILURE TO ISSUE REGULATIONS BY DATE
21 CERTAIN.—If the Secretary fails to issue a final rule
22 under subparagraph (B) of paragraph (1) before the
23 expiration of the period specified in such subpara-
24 graph—

1 (A) the proposed rule issued under sub-
2 paragraph (A) of such paragraph is upon such
3 expiration deemed to be the final rule under
4 subparagraph (B) of such paragraph (and shall
5 remain in effect until the Secretary issues a
6 final rule under such subparagraph); or

7 (B) if no such proposed rule is issued be-
8 fore such expiration, the bylaws and policies
9 specified in paragraph (2) and in effect upon
10 such expiration are deemed to be the final rule
11 under paragraph (1)(B) (and shall remain in
12 effect until the Secretary issues a final rule
13 under such paragraph).

14 **SEC. 11. EFFECTIVE DATES.**

15 (a) IN GENERAL.—The amendments described in this
16 Act are made upon the date of the enactment of this Act.
17 Except as provided in subsection (b), such amendments
18 take effect October 1, 1993, or upon the date of the enact-
19 ment of this Act, whichever occurs later.

20 (b) QUALIFIED ORGAN PROCUREMENT ORGANIZA-
21 TIONS.—The amendments made by section 2 take effect
22 January 1, 1994. Before such date, section 371 of the
23 Public Health Service Act, as in effect on the day before
24 the date of the enactment of this Act, continues to be in
25 effect.



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