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H. R. 2659

IN THE SENATE OF THE UNITED STATES

OCTOBER 6 (legislative day, SEPTEMBER 27), 1993

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

MARCH 24 (legislative day FEBRUARY 22), 1994

Committee discharged

AN ACT

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
5 Marrow 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)—

23 (i) by striking “organization for which
24 grants may be made under subsection (a)

1 is” and inserting “organization described
2 in this subsection is”; and

3 (ii) by striking “paragraph (2)” and
4 inserting “paragraph (3)”;

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

7 (C) in subparagraph (G)—

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

14 (ii) in clause (i)(II), by striking
15 “members” and all that follows and insert-
16 ing the following: “individuals who have re-
17 ceived a transplant of an organ, individuals
18 who are part of the family of an individual
19 who has donated an organ, and individuals
20 who have been medically referred to receive
21 a transplant of an organ (or individuals
22 who are part of the family of individuals
23 who have been so referred), which individ-
24 uals shall in the aggregate constitute not
25 less than $\frac{1}{3}$ of the membership of the

1 board and which members shall, to the ex-
2 tent practicable, be residents of the service
3 area involved,”; and

4 (2) in paragraph (3)—

5 (A) in subparagraph (A), by amending the
6 subparagraph to read as follows:

7 “(A)(i) With respect to each hospital or other
8 entity in its service area that has facilities for organ
9 donations, the organization shall have an effective
10 agreement with the entity under which the entity
11 identifies potential organ donors and notifies the or-
12 ganization, subject to clause (ii).

13 “(ii) The Secretary may waive the requirement
14 of clause (i) to the extent determined by the Sec-
15 retary to be necessary to promote organ donation
16 and the equitable allocation of organs.”;

17 (B)(i) in the matter preceding subpara-
18 graph (A), by striking “shall—” and inserting
19 “shall comply with the following:”;

20 (ii) in each of subparagraphs (B) through
21 (K), by inserting “The organization shall” be-
22 fore the first word of the subparagraph;

23 (iii) in each of subparagraphs (B) through
24 (I), by striking the comma at the end and in-
25 serting a period; and

1 (iv) in subparagraph (J), by striking “,
2 and” and inserting a period;

3 (C) in subparagraph (E)—

4 (i) by inserting “(i)” after the sub-
5 paragraph designation; and

6 (ii) by adding at the end the following
7 clauses:

8 “(ii) The organization shall, subject to clause
9 (iii), ensure that the system under clause (i) allo-
10 cates each type of organ on the basis of a single list,
11 maintained exclusively by the organization, of indi-
12 viduals who have been medically referred to a trans-
13 plant center in the service area of the organization
14 in order to receive a transplant of the type of organ
15 with respect to which the list is maintained, and who
16 are citizens or permanent resident aliens of the
17 United States.

18 “(iii) Upon the request of the organization, the
19 Secretary may, with respect to the service area of
20 the organization, waive the requirement of clause (ii)
21 regarding a single list if the Secretary determines
22 that the waiver is necessary to ensure the equitable
23 allocation of organs of the type involved and maxi-
24 mize the opportunities for successful outcomes of
25 transplants of such organs.”; and

1 (D) in subparagraph (H), by striking “participate” and all that follows through “372”
2 and inserting the following: “be a member of,
3 and abide by the rules and requirements of, the
4 Organ Procurement and Transplantation Net-
5 work established under section 372”.

7 **SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION**
8 **NETWORK.**

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

11 (1) in paragraph (1)—

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

14 (B) by striking subparagraph (B) and in-
15 serting the following subparagraphs:

16 “(B) have a board of directors composed of not
17 more than 32 members, whose membership in-
18 cludes—

19 “(i) representatives of organ procurement
20 organizations, transplant centers, and voluntary
21 health associations; and

22 “(ii) individuals who have received a trans-
23 plant of an organ, individuals who are part of
24 the family of an individual who has donated an
25 organ, and individuals who have been medically

1 referred to receive a transplant of an organ (or
2 individuals who are part of the family of indi-
3 viduals who have been so referred), which indi-
4 viduals shall in the aggregate constitute not less
5 than $\frac{1}{3}$ of the membership of the board; and

6 “(C) establish, through such board of directors,
7 an executive committee and other committees, the
8 chairs of which shall be selected to ensure continuity
9 of leadership for the board.”; and

10 (2) in paragraph (2)—

11 (A) by striking “shall—” in the matter
12 preceding subparagraph (A) and all that follows
13 through the end of clause (i) of such subpara-
14 graph and inserting the following: “shall—

15 “(A) establish (in one location or through re-
16 gional centers)—

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

18 “(I) a national list of individuals who
19 have been medically referred to receive a
20 transplant of the type of organ with re-
21 spect to which the list is maintained and
22 who are citizens or permanent resident
23 aliens of the United States (which list shall
24 include the names of all individuals in-

1 cluded on lists in effect under section
2 371(b)(3)(E)), and

3 “(II) a national list of individuals who
4 have been so referred and who are in the
5 United States but are not such citizens or
6 such aliens, and”; and

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

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

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

13 (iv) by adding at the end the following sub-
14 paragraphs:

15 “(M) establish the condition that, with respect
16 to the type of organ involved, the list under
17 subclause (II) of subparagraph (A)(i) may be consid-
18 ered in allocating an organ only if no individual on
19 the list under subclause (I) of such subparagraph is
20 a medically appropriate recipient for the organ,

21 “(N) submit to the Secretary for review and ap-
22 proval any change in the amount of fees imposed by
23 the Network for the registration of individuals on
24 the lists maintained under subparagraph (A)(i)
25 (which change is deemed to be approved if the Sec-

1 retary does not provide otherwise before the expira-
2 tion of the 30-day period beginning on the date on
3 which the change is submitted to the Secretary),

4 “(O) make available to the Secretary such in-
5 formation, books, and records regarding the Net-
6 work as the Secretary may require, and

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

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

10 (a) IN GENERAL.—

11 (1) TRANSFER OF PROGRAM.—Section 379(a)
12 of the Public Health Service Act (42 U.S.C.
13 274k(a)) is amended in the first sentence by insert-
14 ing after “Secretary” the following: “, acting
15 through the Administrator of the Health Resources
16 and Services Administration,”.

17 (2) TRANSITIONAL AND SAVINGS PROVISIONS.—

18 (A) With respect to amounts made avail-
19 able under appropriations Acts for the purpose
20 of carrying out the program transferred pursu-
21 ant to paragraph (1) from the National Insti-
22 tutes of Health, the transfer of the program
23 may not be construed as affecting the availabil-
24 ity of such amounts for such purpose.

1 (B) The Secretary shall ensure that, for
2 fiscal 1994, the number of employees of the De-
3 partment of Health and Human Services who
4 are engaged in carrying out the program trans-
5 ferred by paragraph (1) is not less than the
6 number of employees who were so engaged on
7 June 28, 1993.

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

11 (1) in subsection (b)—

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

16 (B) in paragraph (5), by striking “recruit”
17 and all that follows and inserting the following:
18 “establish a program for the recruitment of
19 bone marrow donors in accordance with sub-
20 section (k);”;

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

22 (3) by inserting after subsection (i) the follow-
23 ing subsections:

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

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

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

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

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

12 “(C) the physicians involved;

13 “(3) the program provides case management
14 services for such individuals, families, and physi-
15 cians; and

16 “(4) the program meets such other criteria as
17 the Secretary may establish.

18 “(k) RECRUITMENT OF DONORS.—For purposes of
19 subsection (b)(5), a program for the recruitment of bone
20 marrow donors is established in accordance with this sub-
21 section if—

22 “(1) in recruiting an individual to enroll in the
23 Registry, and in each subsequent stage of the proc-
24 ess of recruitment, the program provides to the indi-
25 vidual information regarding the possibility that, if

1 it is determined that it is medically inappropriate for
2 the individual to be a donor for the patient involved,
3 a sibling of the individual may nevertheless be a
4 medically appropriate donor for the patient;

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

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

16 “(4) in the case of an individual described in
17 paragraph (3), the program provides to the individ-
18 ual a general description of the medical condition of
19 the patient involved and an assessment of the possi-
20 bility that the individual is a medically appropriate
21 donor for the patient; and

22 “(5) the program meets such other criteria as
23 the Secretary may establish.”.

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

2 (a) IN GENERAL.—Section 379A(a) of the Public
3 Health Service Act (42 U.S.C. 274l(a)) is amended by
4 striking “conduct” in the matter preceding paragraph (1)
5 and all that follows and inserting the following: “conduct
6 a study for the purpose of—

7 “(1) assessing the extent to which the program
8 carried out under section 379 maintains the con-
9 fidentiality of the identity of individuals who are en-
10 rolled with the Registry;

11 “(2) assessing the extent to which such individ-
12 uals cooperate with the Registry when the Registry
13 requests the individuals to undergo supplemental
14 testing regarding the donation of bone marrow;

15 “(3) assessing, in the case of such individuals
16 who have been determined to be medically appro-
17 priate donors of bone marrow for the patients in-
18 volved, the extent to which such individuals are will-
19 ing to make a donation of bone marrow;

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

25 “(5) assessing the extent to which the case
26 management services provided under section

1 379(j)(3) are effective in assisting patients in receiv-
2 ing the transplants involved;

3 “(6) developing recommendations on improving
4 the program of the Registry, including proposals to
5 increase the number of transplants with successful
6 outcomes while maintaining the confidentiality of the
7 identity of the individuals authorizing the donations
8 of bone marrow;

9 “(7) assessing the extent to which efforts to re-
10 cruit minority individuals to enroll in the Registry
11 have been successful;

12 “(8) assessing, in the case of minority individ-
13 uals who have been medically referred to receive a
14 transplant of bone marrow, the measures that
15 should be implemented to ensure that the Registry
16 provides for such individuals a probability of locating
17 a biologically unrelated, medically appropriate donor
18 that is reasonably equivalent to the probability that
19 exists with respect to Caucasian individuals who
20 have been so referred; and

21 “(9) assessing the extent to which the fees im-
22 posed by transplant centers with respect to the
23 search for a donor of bone marrow, when considered
24 in light of the fees imposed by the Registry, con-

1 stitute a significant obstacle to individuals in obtain-
2 ing a transplant of bone marrow.”.

3 (b) DATE CERTAIN FOR SUBMISSION OF REPORT.—
4 Section 379A(b) of the Public Health Service Act (42
5 U.S.C. 274/(b)) is amended by striking “1 year” and all
6 that follows through “this part” and inserting the follow-
7 ing: “2 years after the date of the enactment of the Organ
8 and Bone Marrow Transplantation Amendments of
9 1993”.

10 **SEC. 6. TRANSFER OF PROGRAMS; MISCELLANEOUS CON-**
11 **FORMING AMENDMENTS.**

12 (a) IN GENERAL.—The Public Health Service Act
13 (42 U.S.C. 201 et seq.), as amended by the preceding pro-
14 visions of this Act, is amended—

15 (1) by striking title XVIII;

16 (2)(A) by transferring sections 371 through
17 377 from the current placement of such sections;

18 (B) by redesignating such sections as sections
19 1801 through 1807, respectively;

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

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

1 “TITLE XVIII—TRANSPLANTATION OF ORGANS
2 AND OF BONE MARROW

3 “PART A—ORGAN TRANSPLANTATION”;

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

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

7 (C) by redesignating such sections as sections
8 1811 and 1813, respectively;

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

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

14 “PART B—NATIONAL BONE MARROW DONOR
15 REGISTRY”;

16 and

17 (4) in title III (as amended by section
18 2008(i)(2)(B) of Public Law 103-43)—

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

21 (B) by redesignating parts J through N as
22 parts H through L, respectively.

23 (b) CROSS-REFERENCES; OTHER CONFORMING
24 AMENDMENTS.—Title XVIII of the Public Health Service

1 Act, as added by subsection (a) of this section, is amend-
2 ed—

3 (1) in section 1801(b)(3)—

4 (A) in subparagraph (C), by striking “sec-
5 tion 372(b)(2)(E)” and inserting “section
6 1802(b)(2)(E)”; and

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

9 (2) in section 1802(b)(2)(A)(i)(I), by striking
10 “section 371(b)(3)(E)” and inserting “section
11 1801(b)(3)(E)”;

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

14 (4) in section 1804—

15 (A) in subsection (a), by striking “section
16 372 or 373” and inserting “section 1802 or
17 1803”;

18 (B) in subsection (b)—

19 (i) in paragraph (1), by striking “sec-
20 tion 371(a)(1)” and inserting “section
21 1801(a)(1)”;

22 (ii) by striking paragraph (2);

23 (iii) by redesignating paragraph (3) as
24 paragraph (2); and

1 (iv) in paragraph (2) (as so redesignig-
2 nated), by striking “section 371(a)(3)”
3 and inserting “section 1801(a)(2)”;

4 (C) in subsection (c), by striking “section
5 371 or 373” each place such term appears and
6 inserting “section 1801 or 1803”; and

7 (D) in subsection (d)—

8 (i) in paragraph (2), by striking “sec-
9 tion 373” and inserting “section 1803”;
10 and

11 (ii) by adding at the end the following
12 paragraph:

13 “(3) The term ‘citizens or permanent resident
14 aliens of the United States’ means individuals who
15 are citizens or nationals of the United States, or
16 who are aliens lawfully admitted for permanent resi-
17 dence in the United States (or otherwise perma-
18 nently residing in the United States under color of
19 law).”;

20 (5) in section 1807, by striking “**SEC.**” and all
21 that follows through “The Comptroller General” in
22 subsection (a) and inserting the following:

23 “STUDY BY GENERAL ACCOUNTING OFFICE

24 “SEC. 1807. (a) IN GENERAL.—The Comptroller
25 General”;

1 (6) in section 1805(3), by striking “section
2 372” and inserting “section 1802”;

3 (7) in section 1811, by striking “**SEC.**” and all
4 that follows through “The Secretary” in the first
5 sentence in subsection (a) and inserting the follow-
6 ing:

7 “NATIONAL REGISTRY

8 “SEC. 1811. (a) ESTABLISHMENT.—The Secretary”;
9 and

10 (8) in section 1813—

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

14 “STUDY BY GENERAL ACCOUNTING OFFICE

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

17 (B) in subsection (a)—

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

20 (ii) in paragraph (4), by striking “sec-
21 tion 379(k)” and inserting “section
22 1811(k)”;

23 (iii) in paragraph (5), by striking
24 “section 379(j)(3)” and inserting “section
25 1811(j)(3)”.

1 **SEC. 7. INFORMATION, EDUCATION, AND TRAINING RE-**
2 **GARDING TRANSPLANTATION OF BONE MAR-**
3 **ROW.**

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

7 “INFORMATION, EDUCATION, AND TRAINING

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

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

14 “(2) training individuals in requesting such do-
15 nations.

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

21 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS FOR NEW**
22 **TITLE XVIII.**

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

1 “PART C—GENERAL PROVISIONS

2 “AUTHORIZATION OF APPROPRIATIONS

3 “SEC. 1821. For the purpose of carrying out this title
4 (other than section 1801(a)(1)), there are authorized to
5 be appropriated \$20,000,000 for fiscal year 1994, and
6 such sums as may be necessary for each of the fiscal years
7 1995 and 1996.”.

8 **SEC. 9. STUDY REGARDING SYSTEM FOR ALLOCATION OF**
9 **ORGANS.**

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

20 (b) REPORT.—Not later than 1 year after the date
21 of the enactment of this Act, the Secretary shall submit
22 to the Committee on Energy and Commerce of the House
23 of Representatives, and to the Committee on Labor and
24 Human Resources of the Senate, a report describing the
25 findings made in the study required in subsection (a) and

1 the actions taken by the Secretary to implement changes
2 consistent with the findings.

3 **SEC. 10. ISSUANCE OF REGULATIONS.**

4 (a) ORGAN PROCUREMENT AND TRANSPLANTATION
5 NETWORK.—

6 (1) IN GENERAL.—

7 (A) Not later than the expiration of the
8 90-day period beginning on the date of the en-
9 actment of this Act, the Secretary of Health
10 and Human Services (in this section referred to
11 as the “Secretary”) shall issue a proposed rule
12 to establish regulations for criteria under part
13 A of title XVIII of the Public Health Service
14 Act (as added by section 6(a) of this Act).

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

20 (2) CONSIDERATION OF CERTAIN BYLAWS AND
21 POLICIES.—In developing regulations under para-
22 graph (1), the Secretary shall consider the bylaws
23 and policies of the United Network for Organ Shar-
24 ing (established by contract under section 1802 of
25 the Public Health Service Act, as redesignated by

1 section 6(a) of this Act), as contained in the docu-
2 ment entitled “Bylaws and Policies of the United
3 Network for Organ Sharing”.

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

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

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

22 (b) NATIONAL BONE MARROW DONOR REGISTRY.—

23 (1) IN GENERAL.—

24 (A) Not later than the expiration of the
25 90-day period beginning on the date of the en-

1 actment of this Act, the Secretary shall issue a
2 proposed rule to establish regulations for stand-
3 ards, criteria, and procedures under part B of
4 title XVIII of the Public Health Service Act (as
5 added by section 6(a) of this Act).

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

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

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

23 (A) the proposed rule issued under sub-
24 paragraph (A) of such paragraph is upon such
25 expiration deemed to be the final rule under

1 subparagraph (B) of such paragraph (and shall
2 remain in effect until the Secretary issues a
3 final rule under such subparagraph); or

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

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

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

17 (b) QUALIFIED ORGAN PROCUREMENT ORGANIZA-
18 TIONS.—

19 (1) IN GENERAL.—Except as provided in para-
20 graph (2), the amendments made by section 2 take
21 effect January 1, 1994. Before such date, section
22 371 of the Public Health Service Act, as in effect on
23 the day before the date of the enactment of this Act,
24 continues to be in effect.

1 (2) ADDITIONAL PROVISION.—The amendment
2 made by section 2(b)(2)(A) (relating to effective
3 agreements with entities with facilities for organ do-
4 nations) takes effect upon the expiration of the 180-
5 day period beginning on the date on which a final
6 rule takes effect under section 10(a). Before such
7 amendment takes effect under the preceding sen-
8 tence, section 371(b)(3)(A) of the Public Health
9 Service Act, as in effect on the day before the date
10 of the enactment of this Act, continues to be in
11 effect.

 Passed the House of Representatives October 5,
1993.

Attest: DONNALD K. ANDERSON,
Clerk.

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