

Union Calendar No. 152

103D CONGRESS
1ST SESSION

H. R. 2659

[Report No. 103-272]

A BILL

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

SEPTEMBER 30, 1993

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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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

SEPTEMBER 30, 1993

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on July 15, 1993]

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,*

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Organ and Bone*
3 *Marrow Transplantation Amendments of 1993”.*

4 **SEC. 2. ORGAN PROCUREMENT ORGANIZATIONS.**

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

7 *(1) by striking paragraphs (2) and (3); and*

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

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

14 *“(i) planning and conducting programs to pro-*
15 *vide information and education to the public on the*
16 *need for organ donations; and*

17 *“(ii) training individuals in requesting such do-*
18 *nations.*

19 *“(B) In making awards of grants and contracts under*
20 *subparagraph (A), the Secretary shall give priority to car-*
21 *rying out the purpose described in such subparagraph with*
22 *respect to minority populations.”.*

23 *(b) REQUIREMENTS REGARDING QUALIFIED ORGAN*
24 *PROCUREMENT ORGANIZATIONS.—Section 371(b) of the*
25 *Public Health Service Act (42 U.S.C. 273(b)) is amended—*

26 *(1) in paragraph (1)—*

1 (A) in the matter preceding subparagraph

2 (A)—

3 (i) by striking “organization for which
4 grants may be made under subsection (a)
5 is” and inserting “organization described in
6 this subsection is”; and

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

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

11 (C) in subparagraph (G)—

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

18 (ii) in clause (i)(II), by striking
19 “members” and all that follows and insert-
20 ing the following: “individuals who have re-
21 ceived a transplant of an organ, individuals
22 who are part of the family of an individual
23 who has donated an organ, and individuals
24 who have been medically referred to receive
25 a transplant of an organ (or individuals

1 *who are part of the family of individuals*
2 *who have been so referred), which individ-*
3 *uals shall in the aggregate constitute not*
4 *less than 1/3 of the membership of the board*
5 *and which members shall, to the extent*
6 *practicable, be residents of the service area*
7 *involved,”; and*

8 (2) *in paragraph (3)—*

9 (A) *in subparagraph (A), by amending the*
10 *subparagraph to read as follows:*

11 “(A)(i) *With respect to each hospital or other en-*
12 *tity in its service area that has facilities for organ do-*
13 *nations, the organization shall have an effective agree-*
14 *ment with the entity under which the entity identifies*
15 *potential organ donors and notifies the organization,*
16 *subject to clause (ii).*

17 “(ii) *The Secretary may waive the requirement*
18 *of clause (i) to the extent determined by the Secretary*
19 *to be necessary to promote organ donation and the eq-*
20 *uitable allocation of organs.”;*

21 (B)(i) *in the matter preceding subpara-*
22 *graph (A), by striking “shall—” and inserting*
23 *“shall comply with the following:”;*

1 (ii) in each of subparagraphs (B) through
2 (K), by inserting “The organization shall” before
3 the first word of the subparagraph;

4 (iii) in each of subparagraphs (B) through
5 (I), by striking the comma at the end and insert-
6 ing a period; and

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

9 (C) in subparagraph (E)—

10 (i) by inserting “(i)” after the sub-
11 paragraph designation; and

12 (ii) by adding at the end the following
13 clauses:

14 “(ii) The organization shall, subject to clause
15 (iii), ensure that the system under clause (i) allocates
16 each type of organ on the basis of a single list, main-
17 tained exclusively by the organization, of individuals
18 who have been medically referred to a transplant cen-
19 ter in the service area of the organization in order to
20 receive a transplant of the type of organ with respect
21 to which the list is maintained, and who are citizens
22 or permanent resident aliens of the United States.

23 “(iii) Upon the request of the organization, the
24 Secretary may, with respect to the service area of the
25 organization, waive the requirement of clause (ii) re-

1 *garding a single list if the Secretary determines that*
2 *the waiver is necessary to ensure the equitable alloca-*
3 *tion of organs of the type involved and maximize the*
4 *opportunities for successful outcomes of transplants of*
5 *such organs.”; and*

6 *(D) in subparagraph (H), by striking “part-*
7 *icipate” and all that follows through “372” and*
8 *inserting the following: “be a member of, and*
9 *abide by the rules and requirements of, the*
10 *Organ Procurement and Transplantation Net-*
11 *work established under section 372”.*

12 **SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION**
13 **NETWORK.**

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

16 *(1) in paragraph (1)—*

17 *(A) in subparagraph (A), by striking “and”*
18 *after the comma at the end; and*

19 *(B) by striking subparagraph (B) and in-*
20 *serting the following subparagraphs:*

21 *“(B) have a board of directors composed of not*
22 *more than 32 members, whose membership includes—*

23 *“(i) representatives of organ procurement*
24 *organizations, transplant centers, and voluntary*
25 *health associations; and*

1 “(ii) individuals who have received a trans-
2 plant of an organ, individuals who are part of
3 the family of an individual who has donated an
4 organ, and individuals who have been medically
5 referred to receive a transplant of an organ (or
6 individuals who are part of the family of indi-
7 viduals who have been so referred), which indi-
8 viduals shall in the aggregate constitute not less
9 than $\frac{1}{3}$ of the membership of the board; and

10 “(C) establish, through such board of directors,
11 an executive committee and other committees, the
12 chairs of which shall be selected to ensure continuity
13 of leadership for the board.”; and

14 (2) in paragraph (2)—

15 (A) by striking “shall—” in the matter pre-
16 ceding subparagraph (A) and all that follows
17 through the end of clause (i) of such subpara-
18 graph and inserting the following: “shall—

19 “(A) establish (in one location or through re-
20 gional centers)—

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

22 “(I) a national list of individuals who
23 have been medically referred to receive a
24 transplant of the type of organ with respect
25 to which the list is maintained and who are

1 *citizens or permanent resident aliens of the*
2 *United States (which list shall include the*
3 *names of all individuals included on lists in*
4 *effect under section 371(b)(3)(E)), and*

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

9 *(B)(i) in subparagraph (J), by striking*
10 *“and” after the comma at the end;*

11 *(ii) in subparagraph (K), by striking the*
12 *period at the end and inserting a comma;*

13 *(iii) in subparagraph (L), by striking the*
14 *period at the end and inserting a comma; and*

15 *(iv) by adding at the end the following sub-*
16 *paragraphs:*

17 *“(M) establish the condition that, with respect to*
18 *the type of organ involved, the list under subclause*
19 *(II) of subparagraph (A)(i) may be considered in al-*
20 *locating an organ only if no individual on the list*
21 *under subclause (I) of such subparagraph is a medi-*
22 *cally appropriate recipient for the organ,*

23 *“(N) submit to the Secretary for review and ap-*
24 *proval any change in the amount of fees imposed by*
25 *the Network for the registration of individuals on the*

1 *lists maintained under subparagraph (A)(i) (which*
2 *change is deemed to be approved if the Secretary does*
3 *not provide otherwise before the expiration of the 30-*
4 *day period beginning on the date on which the change*
5 *is submitted to the Secretary),*

6 *“(O) make available to the Secretary such infor-*
7 *mation, books, and records regarding the Network as*
8 *the Secretary may require, and*

9 *“(P) meet such criteria regarding compliance*
10 *with this part as the Secretary may establish.”.*

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

12 *(a) IN GENERAL.—*

13 *(1) TRANSFER OF PROGRAM.—Section 379(a) of*
14 *the Public Health Service Act (42 U.S.C. 274k(a)) is*
15 *amended in the first sentence by inserting after “Sec-*
16 *retary” the following: “, acting through the Adminis-*
17 *trator of the Health Resources and Services Adminis-*
18 *tration,”.*

19 *(2) TRANSITIONAL AND SAVINGS PROVISIONS.—*

20 *(A) With respect to amounts made available*
21 *under appropriations Acts for the purpose of*
22 *carrying out the program transferred pursuant*
23 *to paragraph (1) from the National Institutes of*
24 *Health, the transfer of the program may not be*

1 *construed as affecting the availability of such*
2 *amounts for such purpose.*

3 *(B) The Secretary shall ensure that, for fis-*
4 *cal 1994, the number of employees of the Depart-*
5 *ment of Health and Human Services who are en-*
6 *gaged in carrying out the program transferred*
7 *by paragraph (1) is not less than the number of*
8 *employees who were so engaged on June 28,*
9 *1993.*

10 *(b) PATIENT ADVOCACY; RECRUITMENT OF DONORS.—*
11 *Section 379 of the Public Health Service Act (42 U.S.C.*
12 *274k) is amended—*

13 *(1) in subsection (b)—*

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

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

23 *(2) by striking subsection (j); and*

24 *(3) by inserting after subsection (i) the following*
25 *subsections:*

1 “(j) *PATIENT ADVOCACY.*—For purposes of subsection
2 (b)(2), a program for patient advocacy is established in ac-
3 cordance 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 to
7 serve as an advocate on behalf of—

8 “(A) individuals who are registered with the
9 Registry to become a recipient of a transplant
10 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 the
17 Secretary may establish.

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

22 “(1) in recruiting an individual to enroll in the
23 Registry, and in each subsequent stage of the process
24 of recruitment, the program provides to the individ-
25 ual information regarding the possibility that, if it is

1 *determined that it is medically inappropriate for the*
2 *individual to be a donor for the patient involved, a*
3 *sibling of the individual may nevertheless be a medi-*
4 *cally 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 possibil-*
20 *ity that the individual is a medically appropriate*
21 *donor for the patient; and*

22 *“(5) the program meets such other criteria as the*
23 *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. 2741(a)) is amended by strik-
4 ing “conduct” in the matter preceding paragraph (1) and
5 all that follows and inserting the following: “conduct a
6 study for the purpose of—

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

11 “(2) assessing the extent to which such individ-
12 uals cooperate with the Registry when the Registry re-
13 quests the individuals to undergo supplemental testing
14 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 man-
26 agement services provided under section 379(j)(3) are

1 *effective in assisting patients in receiving the trans-*
2 *plants 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 should*
15 *be implemented to ensure that the Registry provides*
16 *for such individuals a probability of locating a bio-*
17 *logically unrelated, medically appropriate donor that*
18 *is reasonably equivalent to the probability that exists*
19 *with respect to Caucasian individuals who have been*
20 *so referred; and*

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

1 *nificant obstacle to individuals in obtaining a trans-*
2 *plant of bone marrow.”.*

3 *(b) DATE CERTAIN FOR SUBMISSION OF REPORT.—*
4 *Section 379A(b) of the Public Health Service Act (42 U.S.C.*
5 *2741(b)) is amended by striking “1 year” and all that fol-*
6 *lows through “this part” and inserting the following: “2*
7 *years after the date of the enactment of the Organ and Bone*
8 *Marrow Transplantation Amendments of 1993”.*

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

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

14 *(1) by striking title XVIII;*

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

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

19 *(C) by inserting such sections, in the appropriate*
20 *sequence, after title XVII; and*

21 *(D) by inserting before section 1801 (as so redesi-*
22 *gnated) 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 from
6 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 redес-
13 ignated) the following:

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

15 and

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

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

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

22 (b) CROSS-REFERENCES; OTHER CONFORMING
23 AMENDMENTS.—Title XVIII of the Public Health Service
24 Act, as added by subsection (a) of this section, is amended—

25 (1) in section 1801(b)(3)—

1 (A) in subparagraph (C), by striking “sec-
2 tion 372(b)(2)(E)” and inserting “section
3 1802(b)(2)(E)”; and

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

6 (2) in section 1802(b)(2)(A)(i)(I), by striking
7 “section 371(b)(3)(E)” and inserting “section
8 1801(b)(3)(E)”;

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

11 (4) in section 1804—

12 (A) in subsection (a), by striking “section
13 372 or 373” and inserting “section 1802 or
14 1803”;

15 (B) in subsection (b)—

16 (i) in paragraph (1), by striking “sec-
17 tion 371(a)(1)” and inserting “section
18 1801(a)(1)”;

19 (ii) by striking paragraph (2);

20 (iii) by redesignating paragraph (3) as
21 paragraph (2); and

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

1 (C) in subsection (c), by striking “section
2 371 or 373” each place such term appears and
3 inserting “section 1801 or 1803”; and

4 (D) in subsection (d)—

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

7 (ii) by adding at the end the following
8 paragraph:

9 “(3) The term ‘citizens or permanent resident
10 aliens of the United States’ means individuals who
11 are citizens or nationals of the United States, or who
12 are aliens lawfully admitted for permanent residence
13 in the United States (or otherwise permanently resid-
14 ing in the United States under color of law).”;

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

18 “STUDY BY GENERAL ACCOUNTING OFFICE
19 “SEC. 1807. (a) IN GENERAL.—The Comptroller Gen-
20 eral”;

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

23 (7) in section 1811, by striking “**SEC.**” and all
24 that follows through “The Secretary” in the first sen-
25 tence in subsection (a) and inserting the following:

1 “NATIONAL REGISTRY

2 “SEC. 1811. (a) ESTABLISHMENT.—The Secretary”;

3 and

4 (8) in section 1813—

5 (A) by striking “**SEC.**” and all that follows

6 through “The Comptroller General” in subsection

7 (a) and inserting the following:

8 “STUDY BY GENERAL ACCOUNTING OFFICE

9 “SEC. 1813. (a) IN GENERAL.—The Comptroller Gen-
10 eral”; and

11 (B) in subsection (a)—

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

14 (ii) in paragraph (4), by striking “sec-
15 tion 379(k)” and inserting “section
16 1811(k)”; and

17 (iii) in paragraph (5), by striking
18 “section 379(j)(3)” and inserting “section
19 1811(j)(3)”.

20 **SEC. 7. INFORMATION, EDUCATION, AND TRAINING RE-**
21 **GARDING TRANSPLANTATION OF BONE MAR-**
22 **ROW.**

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

1 *“INFORMATION, EDUCATION, AND TRAINING*

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

5 *“(1) planning and conducting programs to pro-*
6 *vide information and education to the public on the*
7 *need for donations of bone marrow; and*

8 *“(2) training individuals in requesting such do-*
9 *nations.*

10 *“(b) PRIORITIES IN MAKING GRANTS.—In making*
11 *awards of grants and contracts under subsection (a), the*
12 *Secretary shall give priority to carrying out the purpose*
13 *described in such subsection with respect to minority popu-*
14 *lations.”.*

15 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS FOR NEW**

16 **TITLE XVIII.**

17 *Title XVIII of the Public Health Service Act, as added*
18 *by section 6(a) of this Act, is amended by adding at the*
19 *end the following part:*

20 *“PART C—GENERAL PROVISIONS*

21 *“AUTHORIZATION OF APPROPRIATIONS*

22 *“SEC. 1821. For the purpose of carrying out this title*
23 *(other than section 1801(a)(1)), there are authorized to be*
24 *appropriated \$20,000,000 for fiscal year 1994, and such*

1 *sums as may be necessary for each of the fiscal years 1995*
2 *and 1996.”.*

3 **SEC. 9. STUDY REGARDING SYSTEM FOR ALLOCATION OF**
4 **ORGANS.**

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

14 (b) *REPORT.*—*Not later than 1 year after the date of*
15 *the enactment of this Act, the Secretary shall submit to the*
16 *Committee on Energy and Commerce of the House of Rep-*
17 *resentatives, and to the Committee on Labor and Human*
18 *Resources of the Senate, a report describing the findings*
19 *made in the study required in subsection (a) and the actions*
20 *taken by the Secretary to implement changes consistent*
21 *with the findings.*

22 **SEC. 10. ISSUANCE OF REGULATIONS.**

23 (a) *ORGAN PROCUREMENT AND TRANSPLANTATION*
24 *NETWORK.*—

25 (1) *IN GENERAL.*—

1 (A) *Not later than the expiration of the 90-*
2 *day period beginning on the date of the enact-*
3 *ment of this Act, the Secretary of Health and*
4 *Human Services (in this section referred to as*
5 *the “Secretary”)* shall issue a proposed rule to
6 *establish regulations for criteria under part A of*
7 *title XVIII of the Public Health Service Act (as*
8 *added by section 6(a) of this Act).*

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

14 (2) *CONSIDERATION OF CERTAIN BYLAWS AND*
15 *POLICIES.—In developing regulations under para-*
16 *graph (1), the Secretary shall consider the bylaws and*
17 *policies of the United Network for Organ Sharing (es-*
18 *tablished by contract under section 1802 of the Public*
19 *Health Service Act, as redesignated by section 6(a) of*
20 *this Act), as contained in the document entitled “By-*
21 *laws and Policies of the United Network for Organ*
22 *Sharing”.*

23 (3) *FAILURE TO ISSUE REGULATIONS BY DATE*
24 *CERTAIN.—If the Secretary fails to issue a final rule*
25 *under subparagraph (B) of paragraph (1) before the*

1 *expiration of the period specified in such subpara-*
2 *graph—*

3 *(A) the proposed rule issued under subpara-*
4 *graph (A) of such paragraph is upon such expi-*
5 *ration deemed to be the final rule under sub-*
6 *paragraph (B) of such paragraph (and shall re-*
7 *main in effect until the Secretary issues a final*
8 *rule under such subparagraph); or*

9 *(B) if no such proposed rule is issued before*
10 *such expiration, the bylaws and policies specified*
11 *in paragraph (2) and in effect upon such expira-*
12 *tion are deemed to be the final rule under para-*
13 *graph (1)(B) (and shall remain in effect until*
14 *the Secretary issues a final rule under such*
15 *paragraph).*

16 ***(b) NATIONAL BONE MARROW DONOR REGISTRY.—***

17 ***(1) IN GENERAL.—***

18 *(A) Not later than the expiration of the 90-*
19 *day period beginning on the date of the enact-*
20 *ment of this Act, the Secretary shall issue a pro-*
21 *posed rule to establish regulations for standards,*
22 *criteria, and procedures under part B of title*
23 *XVIII of the Public Health Service Act (as added*
24 *by section 6(a) of this Act).*

1 (B) Not later than the expiration of the 1-
2 year period beginning the date of the enactment
3 of this Act, the Secretary shall issue a final rule
4 to establish the regulations described in subpara-
5 graph (A).

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

13 (3) *FAILURE TO ISSUE REGULATIONS BY DATE*
14 *CERTAIN.—If the Secretary fails to issue a final rule*
15 *under subparagraph (B) of paragraph (1) before the*
16 *expiration of the period specified in such subpara-*
17 *graph—*

18 (A) *the proposed rule issued under subpara-*
19 *graph (A) of such paragraph is upon such expi-*
20 *ration deemed to be the final rule under sub-*
21 *paragraph (B) of such paragraph (and shall re-*
22 *main in effect until the Secretary issues a final*
23 *rule under such subparagraph); or*

24 (B) *if no such proposed rule is issued before*
25 *such expiration, the bylaws and policies specified*

1 *in paragraph (2) and in effect upon such expira-*
2 *tion are deemed to be the final rule under para-*
3 *graph (1)(B) (and shall remain in effect until*
4 *the Secretary issues a final rule under such*
5 *paragraph).*

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

7 *(a) IN GENERAL.—The amendments described in this*
8 *Act are made upon the date of the enactment of this Act.*
9 *Except as provided in subsection (b), such amendments take*
10 *effect October 1, 1993, or upon the date of the enactment*
11 *of this Act, whichever occurs later.*

12 *(b) QUALIFIED ORGAN PROCUREMENT ORGANIZA-*
13 *TIONS.—*

14 *(1) IN GENERAL.—Except as provided in para-*
15 *graph (2), the amendments made by section 2 take ef-*
16 *fect January 1, 1994. Before such date, section 371 of*
17 *the Public Health Service Act, as in effect on the day*
18 *before the date of the enactment of this Act, continues*
19 *to be in effect.*

20 *(2) ADDITIONAL PROVISION.—The amendment*
21 *made by section 2(b)(2)(A) (relating to effective agree-*
22 *ments with entities with facilities for organ dona-*
23 *tions) takes effect upon the expiration of the 180-day*
24 *period beginning on the date on which a final rule*
25 *takes effect under section 10(a). Before such amend-*

1 *ment takes effect under the preceding sentence, section*
2 *371(b)(3)(A) of the Public Health Service Act, as in*
3 *effect on the day before the date of the enactment of*
4 *this Act, continues to be in effect.*

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