

**Calendar No. 377**

104<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 1324**

**[Report No. 104-256]**

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**A BILL**

To amend the Public Health Service Act to revise and extend the solid-organ procurement and transplantation programs, and the bone marrow donor program, and for other purposes.

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APRIL 22, 1996

Reported with an amendment

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**IN THE SENATE OF THE UNITED STATES**

OCTOBER 17 (legislative day, OCTOBER 10), 1995

Mrs. KASSEBAUM (for herself, Mr. KENNEDY, and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

APRIL 22, 1996

Reported by Mrs. KASSEBAUM, with an amendment

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

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**A BILL**

To amend the Public Health Service Act to revise and extend the solid-organ procurement and transplantation programs, and 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 “Organ and Bone Mar-  
3 row Transplant Program Reauthorization Act of 1995”.

4 **TITLE I—SOLID ORGAN**  
5 **TRANSPLANT PROGRAM**

6 **SEC. 101. SHORT TITLE.**

7 This title may be cited as the “Solid-Organ Trans-  
8 plant Program Reauthorization Act of 1995”.

9 **SEC. 102. ORGAN PROCUREMENT ORGANIZATIONS.**

10 (a) IN GENERAL.—Subsection (a) of section 371 of  
11 the Public Health Service Act (42 U.S.C. 273(a)) is  
12 amended to read as follows:

13 “(a)(1) The Secretary may enter into cooperative  
14 agreements and contracts with qualified organ procure-  
15 ment organizations described in subsection (b) and other  
16 public or nonprofit private entities for the purpose of in-  
17 creasing organ donation through approaches such as—

18 “(A) the planning and conducting of programs  
19 to provide information and education to the public  
20 on the need for organ donations;

21 “(B) the training of individuals in requesting  
22 such donations;

23 “(C) the provision of technical assistance to  
24 organ procurement organizations and other entities  
25 that can contribute to organ donation;

1           ~~“(D) the performance of research and the per-~~  
 2           ~~formance of demonstration programs by organ pro-~~  
 3           ~~curement organizations and other entities that may~~  
 4           ~~increase organ donation;~~

5           ~~“(E) the voluntary consolidation of organ pro-~~  
 6           ~~curement organizations and tissue banks; or~~

7           ~~“(F) increasing organ donation and access to~~  
 8           ~~transplantation with respect to minority populations~~  
 9           ~~for which there is a greater degree of organ short-~~  
 10          ~~ages relative to the general population.~~

11          ~~“(2)(A) In entering into cooperative agreements and~~  
 12          ~~contracts under subparagraphs (A) and (B) of paragraph~~  
 13          ~~(1), the Secretary shall give priority to increasing dona-~~  
 14          ~~tions and improving consent rates for the purpose de-~~  
 15          ~~scribed in such paragraph.~~

16          ~~“(B) In entering into cooperative agreements and~~  
 17          ~~contracts under paragraph (1)(C), the Secretary shall give~~  
 18          ~~priority to carrying out the purpose described in such~~  
 19          ~~paragraph with respect to increasing donations from both~~  
 20          ~~organ procurement organizations and hospitals.”.~~

21          ~~(b) QUALIFIED ORGAN PROCUREMENT ORGANIZA-~~  
 22          ~~TIONS.—Section 371(b) of such Act (42 U.S.C. 273(b))~~  
 23          ~~is amended—~~

24                  ~~(1) in paragraph (1)—~~

1           (A) in the matter preceding subparagraph

2           (A)—

3                   (i) by striking “for which grants may  
4                   be made under subsection (a)” and insert-  
5                   ing “described in this section”; and

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

8           (B) by realigning the margin of subpara-  
9           graph (E) so as to align with the margin of  
10           subparagraph (D); and

11           (C) in subparagraph (G)—

12                   (i) in the matter preceding clause (i),  
13                   by striking “directors or an advisory  
14                   board” and inserting “directors (or an ad-  
15                   visory board, in the case of a hospital-  
16                   based organ procurement organization es-  
17                   tablished prior to September 1, 1993)”;  
18                   and

19                   (ii) in clause (i)—

20                           (I) by striking “composed of” in  
21                           the matter preceding subclause (I)  
22                           and inserting “composed of a reason-  
23                           able balance of”;

24                           (II) by inserting before the  
25                           comma in subclause (II) the following:

1 “, including individuals who have re-  
 2 ceived a transplant of an organ (or  
 3 transplant candidates); and individ-  
 4 uals who are part of the family of an  
 5 individual who has donated or re-  
 6 ceived an organ or who is a transplant  
 7 candidate”;

8 (III) by striking subclause (IV)  
 9 and inserting the following new sub-  
 10 clause:

11 “(IV) physicians or other health care  
 12 professionals with knowledge and skill in  
 13 the field of neurology, emergency medicine,  
 14 or trauma surgery”; and

15 (IV) in subclause (V), by striking  
 16 “a member” and all that follows  
 17 through the comma and insert the fol-  
 18 lowing: “a member who is a surgeon  
 19 or physician who has privileges to  
 20 practice in such centers and who is  
 21 actively and directly involved in caring  
 22 for transplant patients,”;

23 (2) by striking paragraph (2);

24 (3) by redesignating paragraph (3) as para-  
 25 graph (2);

1           (4) in paragraph (2) (as so redesignated)—

2                   (A) in subparagraph (A)—

3                           (i) by striking “a substantial major-  
4                           ity” and inserting “all”;

5                           (ii) by striking “donation,” and in-  
6                           serting “donation, unless they have been  
7                           previously granted by the Secretary a waiv-  
8                           er from paragraph (1)(A) or have waivers  
9                           pending under section 1138 of the Social  
10                          Security Act”; and

11                          (iii) by adding at the end thereof the  
12                          following: “except that the Secretary may  
13                          waive the requirements of this subpara-  
14                          graph upon the request of the organ pro-  
15                          curement organization if the Secretary de-  
16                          termines that such an agreement would  
17                          not be helpful in promoting organ dona-  
18                          tion.”;

19                          (B) by redesignating subparagraphs (B)  
20                          through (K) as subparagraphs (D) through  
21                          (M), respectively;

22                          (C) by inserting after subparagraph (A)  
23                          the following new subparagraphs:

24                           “(B) conduct and participate in systematic ef-  
25                           forts, including public education, to increase the

1 number of potential donors, including minority popu-  
 2 lations for which there is a greater degree of organ  
 3 shortage than that of the general population,

4 “(C) be a member of and abide by the rules and  
 5 requirements of the Organ Procurement and Trans-  
 6 plantation Network (referred to in this part as the  
 7 ‘Network’) established under section 372,”;

8 (D) by inserting before the comma in sub-  
 9 paragraph (G) (as so redesignated) the follow-  
 10 ing: “, which system shall, at a minimum, allo-  
 11 cate each type of organ on the basis of—

12 “(i) a single list encompassing the entire  
 13 service area;

14 “(ii) a list that encompasses at least an en-  
 15 tire State;

16 “(iii) a list that encompasses an approved  
 17 alternative local unit (as defined in paragraph  
 18 (3)) that is approved by the Network and the  
 19 Secretary; or

20 “(iv) a list that encompasses another allo-  
 21 cation system which has been approved by the  
 22 Network and the Secretary,

23 of individuals who have been medically referred to a  
 24 transplant center in the service area of the organiza-  
 25 tion in order to receive a transplant of the type of



1 organ with respect to which the list is maintained  
 2 and had been placed on an organ specific waiting  
 3 list,”;

4 (E) by inserting before the comma in sub-  
 5 paragraph (I) (as so redesignated) the follow-  
 6 ing: “and work with local transplant centers to  
 7 ensure that such centers are actively involved  
 8 with organ donation efforts”; and

9 (F) by inserting after “evaluate annually”  
 10 in subparagraph (L) (as so redesignated) the  
 11 following “and submit data to the Network con-  
 12 tractor on” the effectiveness of the organiza-  
 13 tion,”; and

14 (5) by adding at the end thereof the following  
 15 new paragraph:

16 “(3)(A) As used in paragraph (2)(G), the term ‘alter-  
 17 native local unit’ means—

18 “(i) a unit composed of two or more organ pro-  
 19 curement organizations; or

20 “(ii) a subdivision of an organ procurement or-  
 21 ganization that operates as a distinct procurement  
 22 and distribution unit as a result of special geo-  
 23 graphic, rural, or minority population concerns but  
 24 that is not composed of any subunit of a metropoli-  
 25 tan statistical area.

1       “(B) The Network shall make recommendations to  
 2 the Secretary concerning the approval or denial of alter-  
 3 native local units. The Network shall assess whether the  
 4 alternative local units will better promote organ donation  
 5 and the equitable allocation of organs.

6       “(C) The Secretary shall approve or deny any alter-  
 7 native local unit designation recommended by the Net-  
 8 work. The Secretary shall have 60 days, beginning on the  
 9 date on which the application is submitted to the Sec-  
 10 retary, to approve or deny the recommendations of the  
 11 Network under subparagraph (B) with respect to the ap-  
 12 plication of the alternative local unit.”.

13       (e) AFFECT OF AMENDMENTS.—The amendments  
 14 made by subsection (b) shall not be construed to affect  
 15 the provisions of section 1138(a) of the Social Security  
 16 Act (42 U.S.C. 1320b-8(a)).

17       (d) EFFECTIVE DATE.—The amendments made by  
 18 subsection (b) shall apply to organ procurement organiza-  
 19 tions and the Organ Procurement and Transplantation  
 20 Network beginning January 1, 1996.

21 **SEC. 103. ORGAN PROCUREMENT AND TRANSPLANTATION**  
 22 **NETWORK.**

23       (a) OPERATION.—Subsection (a) of section 372 of  
 24 the Public Health Service Act (42 U.S.C. 274(a)) is  
 25 amended to read as follows:

1 “(a)(1) Congress finds that—

2 “(A) it is in the public interest to maintain and  
3 improve a durable system for promoting and sup-  
4 porting a central network to assist organ procure-  
5 ment organizations in the nationwide distribution of  
6 organs among transplant patients;

7 “(B) it is desirable to continue the partnership  
8 between public and private enterprise, by continuing  
9 to provide Federal Government oversight and assist-  
10 ance for services performed by the Network; and

11 “(C) the Federal Government should actively  
12 oversee Network activities to ensure that the policies  
13 and procedures of the Network for serving patient  
14 and donor families and procuring and distributing  
15 organs are fair, efficient and in compliance with all  
16 applicable legal rules and standards; however, the  
17 initiative and primary responsibility for establishing  
18 medical criteria and standards for organ procure-  
19 ment and transplantation stills resides with the Net-  
20 work.

21 “(2) The Secretary shall provide by contract for the  
22 operation of the Network which shall meet the require-  
23 ments of subsection (b).

24 “(3) The Network shall be recognized as a private  
25 entity that has an expertise in organ procurement and

1 transplantation with the primary purposes of encouraging  
2 organ donation, maintaining a ‘wait list’, and operating  
3 and monitoring an equitable and effective system for allo-  
4 cating organs to transplant recipients, and shall report to  
5 the Secretary instances of continuing noncompliance with  
6 policies (or when promulgated, rules) and requirements of  
7 the Network.

8       “(4) The Network may assess a fee (to be known as  
9 the ‘patient registration fee’), to be collected by the con-  
10 tractor for listing each potential transplant recipient on  
11 its national organ matching system, in an amount which  
12 is reasonable and customary and determined by the Net-  
13 work and approved as such by the Secretary. The patient  
14 registration fee shall be calculated so as to be sufficient  
15 to cover the Network’s reasonable costs of operation in  
16 accordance with this section. The Secretary shall have 60  
17 days, beginning on the date on which the written applica-  
18 tion justifying the proposed fee as reasonable is submitted  
19 to the Secretary, to provide the Network with a written  
20 determination and rationale for such determination that  
21 the proposed increase is not reasonable and customary and  
22 that the Secretary disapproves the recommendation of the  
23 Network under this paragraph with respect to the change  
24 in fee for listing each potential transplant recipient.

1       “(5) Any increase in the patient registration fee shall  
2 be limited to an increase that is reasonably required as  
3 a result of—

4               “(A) increases in the level or cost of contract  
5 tasks and other activities related to organ procure-  
6 ment and transplantation; or

7               “(B) decreases in expected revenue from patient  
8 registration fees available to the contractor.

9 The patient registration fees shall not be increased more  
10 than once during each year.

11       “(6) All fees collected by the Network contractor  
12 under paragraph (4) shall be available to the Network  
13 without fiscal year limitation. The contract with the Net-  
14 work contractor shall provide that expenditures of such  
15 funds (including patient registration fees collected by the  
16 contractor and or contract funds) are subject to an annual  
17 audit under the provisions of the Office of Management  
18 and Budget Circular No. A-133 entitled ‘Audits of Insti-  
19 tutions of Higher Learning and Other Nonprofit Institu-  
20 tions’ to be performed by the Secretary or an authorized  
21 auditor at the discretion of the Secretary. A report con-  
22 cerning the audit and recommendations regarding expend-  
23 itures shall be submitted to the Network, the contractor,  
24 and the Secretary.

1       “(7) The Secretary may institute and collect a data  
2 management fee from transplant hospitals and organ pro-  
3 curement organizations. Such fees shall be directed to and  
4 shall be sufficient to cover—

5               “(A) the costs of the operation and administra-  
6 tion of the Scientific Registry in accordance with the  
7 contract under section 373; and

8               “(B) the costs of contracts and cooperative  
9 agreements to support efforts to increase organ do-  
10 nation under section 371.

11 Such data management fee shall be set annually by the  
12 Network in an amount determined by the Network, in con-  
13 sultation with the Secretary, and approved by the Sec-  
14 retary. Such data management fee shall be calculated to  
15 be sufficient to cover the reasonable costs of operation in  
16 accordance with section 373. Such data management fee  
17 shall be calculated based on the number of transplants  
18 performed or facilitated by each transplant hospital or  
19 center, or organ procurement organization. The per trans-  
20 plant data management fee shall be divided so that the  
21 patient specific transplant center will pay 80 percent and  
22 the procuring organ procurement organization will pay 20  
23 percent of the per transplant data management fee. Such  
24 fees shall be available to the Secretary and the contractor  
25 operating the Scientific Registry without fiscal year limita-

1 tion. The expenditure (including fees or contract funds)  
 2 of such fees by the contractor shall be subject to an annual  
 3 independent audit (performed by the Secretary or an au-  
 4 thorized auditor at the discretion of the Secretary) and  
 5 reported along with recommendations regarding such ex-  
 6 penditures, to the Network, the contractor and the Sec-  
 7 retary.

8       “(8) The Secretary and the Comptroller General shall  
 9 have access to all data collected by the contractor or con-  
 10 tractors in carrying out its responsibilities under the con-  
 11 tract under this section and section 373.”

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

14               (1) in paragraph (1)(B)—

15                       (A) in clause (i)—

16                               (i) by striking “(including organiza-  
 17 tions that have received grants under sec-  
 18 tion 371)”;

19                               (ii) by striking “; and” at the end  
 20 thereof and inserting “(including both indi-  
 21 viduals who have received a transplant of  
 22 an organ (or transplant candidates), indi-  
 23 viduals who are part of the family of indi-  
 24 viduals who have donated or received an  
 25 organ, the number of whom shall make up

1 a reasonable portion of the total number of  
2 board members); and the Division of  
3 Organ Transplantation of the Bureau of  
4 Health Resources Development (the Health  
5 Resources and Services Administration)  
6 shall be represented at all meetings except  
7 for those pertaining to the Network con-  
8 tractor's internal business;";

9 (B) in clause (ii)—

10 (i) by inserting "including a patient  
11 affairs committee and a minority affairs  
12 committee" after "committees,"; and

13 (ii) by striking the period; and

14 (C) by adding at the end thereof the fol-  
15 lowing new clauses:

16 "(iii) that shall include representation by a  
17 member of the Division of Organ Transplan-  
18 tation of the Bureau of Health Resources De-  
19 velopment (the Health Resources and Services  
20 Administration) as a representative at all meet-  
21 ings (except for those portions of committee  
22 meetings pertaining to the Network contractor's  
23 internal business) of all committees (including  
24 the executive committee, finance committee,  
25 nominating committee, and membership and



1 professional standards committee) under clause  
2 (ii);

3 “(iv) that may include a member from an  
4 organ procurement organization on all commit-  
5 tees under clause (ii); and

6 “(v) that may include physicians or other  
7 health care professionals with knowledge and  
8 skill in the field of neurology, emergency medi-  
9 cine, and trauma surgery on all committees  
10 under clause (ii).”; and

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in the matter preceding clause (i),  
14 by striking “or through regional centers”  
15 and inserting “and at each Organ Procure-  
16 ment Organization”; and

17 (ii) by striking clause (i) and inserting  
18 the following new clause:

19 “(i) with respect to each type of trans-  
20 plant, a national list of individuals who have  
21 been medically referred to receive a transplant  
22 of the type of organs with respect to which the  
23 list is maintained (which list shall include the  
24 names of all individuals included on lists in ef-  
25 fect under section 371(b)(2)(G)), and”;

1           ~~(B)~~ in subparagraph ~~(B)~~, by inserting “,  
2 including requirements under section 371(b),”  
3 after “membership criteria”;

4           ~~(C)~~ by redesignating subparagraphs ~~(E)~~  
5 through ~~(L)~~, as subparagraphs ~~(F)~~ through  
6 ~~(M)~~, respectively;

7           ~~(D)~~ by inserting after subparagraph ~~(D)~~,  
8 the following new subparagraph:

9           “~~(E)~~ assist and monitor organ procurement or-  
10 ganizations in the equitable distribution of organs  
11 among transplant patients,”;

12           ~~(E)~~ in subparagraph ~~(K)~~ (as so redesign-  
13 ated), by striking “and” at the end thereof;

14           ~~(F)~~ in subparagraph ~~(L)~~ (as so redesign-  
15 ated), by striking the period and inserting “,  
16 including making recommendations to organ  
17 procurements organizations and the Secretary  
18 based on data submitted to the Network under  
19 section 371(b)(2)(L),”;

20           ~~(G)~~ in subparagraph ~~(M)~~ (as so redesign-  
21 ated)—

22           (i) by striking “annual” and inserting  
23 “biennial”;

24           (ii) by striking “the comparative costs  
25 and”;

1                   (iii) by striking the period and insert-  
2                   ing the following: “, including survival in-  
3                   formation, waiting list information, and in-  
4                   formation pertaining to the qualifications  
5                   and experience of transplant surgeons and  
6                   physicians affiliated with the specific Net-  
7                   work programs,”; and

8                   (H) by adding at the end thereof the fol-  
9                   lowing new subparagraphs:

10                   “(N) submit to the Secretary for approval a  
11                   written notice containing a justification, as reason-  
12                   able and customary, of any proposed increase in the  
13                   patient registration fees as maintained under sub-  
14                   paragraph (A)(i), such change to be considered as so  
15                   approved if the Secretary does not provide written  
16                   notification otherwise prior to the expiration of the  
17                   60-day period beginning on the date on which the  
18                   notice of proposed change is submitted to the Sec-  
19                   retary,

20                   “(O) make available to the Secretary such in-  
21                   formation, books, and records regarding the Net-  
22                   work as the Secretary may require,

23                   “(P) submit to the Secretary, in a manner pre-  
24                   scribed by the Secretary, an annual report concern-

1 ing the scientific and clinical status of organ dona-  
 2 tion and transplantation; and

3 “(Q) meet such other criteria regarding compli-  
 4 ance with this part as the Secretary may establish.”.

5 (e) PROCEDURES.—Section 372(e) of the Public  
 6 Health Service Act (42 U.S.C. 274(e)) is amended—

7 (1) in paragraph (1), by striking “and” at the  
 8 end thereof;

9 (2) in paragraph (2), by striking the period and  
 10 inserting a semicolon; and

11 (3) by adding at the end thereof the following  
 12 new paragraphs:

13 “(3) working through and with, the Network  
 14 contractor to define priorities; and

15 “(4) working through, working with, and direct-  
 16 ing the Network contractor to respond to new  
 17 emerging issues and problems.”.

18 (d) EXPANSION OF ACCESS.—Section 372 of the  
 19 Public Health Service Act (42 U.S.C. 274) is amended  
 20 by adding at the end thereof the following new subsection:

21 “(d) EXPANSION OF ACCESS TO COMMITTEES AND  
 22 BOARD OF DIRECTORS.—Not later than 1 year after the  
 23 completion of the Institute of Medicine study, the Network  
 24 contractor, in consultation with the Network and the Sec-  
 25 retary, shall implement the study recommendations relat-

1 ing to the access of all interested constituencies and orga-  
 2 nizations to membership on the Network Board of Direc-  
 3 tors and all of its committees. Ensuring the reasonable  
 4 mix of minorities shall be a priority of the plan for imple-  
 5 mentation.”.

6 (c) REGULATIONS.—

7 (1) IN GENERAL.—Not later than the expira-  
 8 tion of the 1-year period beginning on the date of  
 9 enactment of this Act, the Secretary of Health and  
 10 Human Services shall issue a final rule to establish  
 11 the regulations for criteria under part H of title III  
 12 of the Public Health Service Act (42 U.S.C. 273 et  
 13 seq.).

14 (2) CONSIDERATION OF CERTAIN BYLAWS AND  
 15 POLICIES.—In developing regulations under para-  
 16 graph (1), the Secretary shall consider the bylaws  
 17 and policies of the Network.

18 (3) FAILURE TO ISSUE REGULATIONS BY DATE  
 19 CERTAIN.—

20 (A) IN GENERAL.—If the Secretary fails to  
 21 issue a final rule under paragraph (1) prior to  
 22 the expiration of the period referred to in such  
 23 paragraph, the notice of proposed rule making  
 24 issued by the Secretary on September 8, 1994,  
 25 (which shall be referred to as the “proposed

1 final rule”) shall be deemed to be the final rule  
 2 under paragraph (1), and shall remain in effect  
 3 until the Secretary issues a final rule under  
 4 such paragraph.

5 (B) CONFLICT BETWEEN RULE AND POL-  
 6 ICY.—Except as otherwise provided in this  
 7 paragraph, and effective as described in para-  
 8 graph (1), if the Secretary determines that  
 9 there is a conflict between the proposed final  
 10 rule and Network policy, the Secretary shall en-  
 11 sure that the proposed final rule is enforced  
 12 until the final rule is issued.

13 (C) NEW POLICIES.—The Secretary shall  
 14 require that new policies developed after Sep-  
 15 tember 8, 1994, (the date of the publication of  
 16 the “Notice of Proposed Rule Making”) shall go  
 17 through the policy development process as de-  
 18 scribed in section 121.3(a)(6) of such “Notice  
 19 of Proposed Rule Making”.

20 **SEC. 104. TERMS AND CONDITIONS OF GRANTS AND CON-**  
 21 **TRACTS.**

22 Section 374 of the Public Health Service Act (42  
 23 U.S.C. 274b) is amended—

24 (1) in subsection (b)(2), by striking “two  
 25 years” and inserting “(three years)”;

1           (2) in subsection (c)—

2                   (A) by redesignating paragraph (1) and

3           (2) as paragraphs (2) and (3), respectively; and

4                   (B) by inserting before paragraph (2) (as

5           so redesignated) the following new paragraph:

6           “(1) The Secretary shall annually withhold not to ex-  
7           ceed \$250,000 or 10 percent of the amount of the data  
8           management fees collected under section 372 (whichever  
9           is greater) to be used to fund contracts as described in  
10          section 371.”;

11                  (3) by redesignating subsection (d) as sub-  
12          section (e); and

13                  (4) by adding at the end thereof the following  
14          new subsection:

15          “(d) No contract in excess of \$25,000 may be made  
16          under this part using funds withheld under subsection  
17          (e)(1) unless an application for such contract has been  
18          submitted to the Secretary, recommended by the Network  
19          and approved by the Secretary. Such an application shall  
20          be in such form and be submitted in such a manner as  
21          the Secretary shall prescribe.”.

22       **SEC. 105. ADMINISTRATION.**

23           Section 375 of the Public Health Service Act (42  
24       U.S.C. 274e) is amended—

1           (1) in section 375 (42 U.S.C. 274e), by insert-  
2           ing before the dash the following: “oversee the Net-  
3           work, the Scientific Registry and to”;

4           (2) in paragraph (3)—

5                 (A) by inserting “and oversight” after “as-  
6                 sistance”;

7                 (B) by striking “in the health care sys-  
8                 tem”; and

9                 (C) by striking “and” at the end thereof;

10           (3) in paragraph (4), by striking the period and  
11           inserting “; and”; and

12           (4) by adding at the end thereof the following  
13           new paragraph:

14                 “(5) through contract, prepare a triennial organ  
15                 procurement organization specific data report (the  
16                 initial report to be completed not later than 18  
17                 months after the date of enactment of this para-  
18                 graph) that includes—

19                         “(A) data concerning the effectiveness of  
20                         each organ procurement organization in acquir-  
21                         ing potentially available organs, particularly  
22                         among minority populations;

23                         “(B) data concerning the variation of pro-  
24                         curement across hospitals within the organ pro-  
25                         curement organization region;



1           “(C) a plan to increase procurement, par-  
 2           ticularly among minority populations for which  
 3           there is a greater degree of organ shortages rel-  
 4           ative to the general population; and

5           “(D) a plan to increase procurement at  
 6           hospitals with low rates of procurement.”.

7   **SEC. 106. STUDY AND REPORT.**

8           Section 377 of the Public Health Service Act (42  
 9   U.S.C. 174f) is amended to read as follows:

10 **“SEC. 377. STUDY AND REPORT.**

11       “(a) EVALUATION BY THE INSTITUTE OF MEDI-  
 12   CINE.—

13           “(1) IN GENERAL.—The Secretary shall enter  
 14       into a contract with a public or nonprofit private en-  
 15       tity to conduct a study and evaluation of—

16           “(A) the role of and the impact of the Fed-  
 17       eral Government in the oversight and support  
 18       of solid-organ transplantation; the Network  
 19       (which on the date of enactment of this section  
 20       carries out its functions by government con-  
 21       tract) and the solid organ transplantation sci-  
 22       entific registry; and

23           “(B) the access of all interested constitu-  
 24       encies and organizations to membership on the

1 Network board of directors and all Network  
2 committees;

3 “(2) INSTITUTE OF MEDICINE.—The Secretary  
4 shall request the Institute of Medicine of the Na-  
5 tional Academy of Sciences to enter into the contract  
6 under paragraph (1) to conduct the study and eval-  
7 uation described in such paragraph. If the Institute  
8 declines to conduct the study and evaluation under  
9 such paragraph, the Secretary shall carry out such  
10 activities through another public or nonprofit private  
11 entity.

12 (b) REPORT.—Not later than 2 years after the date  
13 of enactment of this section, the Institute of Medicine (or  
14 other entity as the case may be) shall complete the study  
15 required under subsection (a)(1) and prepare and submit  
16 to the Committee on Labor and Human Resources of the  
17 Senate, a report describing the findings made as a result  
18 of the study.”.

19 **SEC. 107. GENERAL PROVISIONS.**

20 (a) CONTRACTS.—Section 374 of the Public Health  
21 Service Act (42 U.S.C. 274b) is amended—

22 (1) in the section heading, by striking  
23 “GRANTS AND”;

1           (2) in subsection (a), by striking “grant may be  
2           made under this part or contract” and inserting  
3           “contract may be”;

4           (3) in subsection (b)—

5           (A) in paragraph (1)—

6           (i) by striking “grant” and inserting  
7           “contract”; and

8           (ii) by striking “and may not exceed  
9           \$100,000”;

10          (B) by striking paragraph (2);

11          (C) by redesignating paragraph (3) as  
12          paragraph (2); and

13          (D) in paragraph (2) (as so redesign-  
14          ated)—

15          (i) by striking “Grants or contracts”  
16          and inserting “Contracts”; and

17          (ii) by striking “371(a)(3)” and in-  
18          serting “371(a)(2)”;

19          (4) in subsection (c)—

20          (A) by striking “grant or” each place that  
21          such appears; and

22          (B) in paragraph (1), by striking “grants  
23          and”; and

1           (5) in subsection (d)(2), by striking “and for  
2           purposes of section 373, such term includes bone  
3           marrow”.

4           (b) REPEAL.—Sections 376 and 378 of the Public  
5 Health Service Act (42 U.S.C. 274d and 274g) are re-  
6 pealed.

7 **SEC. 108. AUTHORIZATION OF APPROPRIATION.**

8           Part H of title III of the Public Health Service Act  
9 (42 U.S.C. 273 et seq.) is amended by adding at the end  
10 thereof the following new section:

11 **“SEC. 378. AUTHORIZATION OF APPROPRIATIONS.**

12           “There are authorized to be appropriated to carry out  
13 sections 371, 372, and 373, \$1,950,000 for fiscal year  
14 1997, and \$1,100,000 for fiscal year 1998, and to carry  
15 out section 371, \$250,000 for each of the fiscal years 1999  
16 through 2001.”.

17 **SEC. 109. EFFECTIVE DATES.**

18           The amendments made by this title shall become ef-  
19 fective on the date of enactment of this Act.

20           **TITLE II—BONE MARROW**  
21           **DONOR PROGRAM**

22 **SEC. 201. SHORT TITLE.**

23           This title may be cited as the “Bone Marrow Trans-  
24 plantation Program Reauthorization Act of 1995”.

1 **SEC. 202. REAUTHORIZATION.**

2 (a) ESTABLISHMENT OF DONOR REGISTRY.—Section  
3 379(a) of the Public Health Service Act (42 U.S.C.  
4 274k(a)) is amended—

5 (1) by striking “‘Registry’” and inserting  
6 “‘Donor Registry’”;

7 (2) by inserting after the end parenthesis the  
8 following: “the primary purpose of which shall be in-  
9 creasing unrelated donor marrow transplants,”; and

10 (2) by adding at the end thereof the following:  
11 “With respect to the board of directors—

12 “(1) each member of the board shall serve for  
13 a term of 2 years; and each such member may serve  
14 as many as three consecutive 2-year terms;

15 “(2) a member of the board may continue to  
16 serve after the expiration of the term of such mem-  
17 ber until a successor is appointed;

18 “(3) to ensure the continuity of the board; not  
19 more than one-third of the board shall be composed  
20 of members newly appointed each year;

21 “(4) all appointed and elected positions within  
22 committees established by the board shall be for 2-  
23 year periods;

24 “(5) the terms of approximately one-third of  
25 the members of each such committee will be subject  
26 each year to reappointment or replacement;

1           “(6) no individual shall serve more than three  
2       consecutive 2-year terms on any such committee;  
3       and

4           “(7) the board and committees shall be com-  
5       posed of a reasonable balance of representatives of  
6       donor centers, transplant centers, blood banks, mar-  
7       row transplant recipients, individuals who are family  
8       members of an individual who has required, received,  
9       or is registered with the Donor Registry to become  
10      a recipient of a transplant from a biologically unre-  
11      lated marrow donor, with nonvoting representatives  
12      from the Naval Medical Research and Development  
13      Command and the Division of Organ Transplan-  
14      tation of the Bureau of Health Resources Develop-  
15      ment (of the Health Resources and Services Admin-  
16      istration).”.

17       (b) PROGRAM FOR UNRELATED MARROW TRANS-  
18      PLANTS.—Section 379(b) of such Act (42 U.S.C. 274k(b))  
19      is amended—

20           (1) in paragraph (4) to read as follows:

21           “(4) provide information to physicians, other  
22      health care professionals, and the public regarding  
23      the availability of unrelated marrow transplantation  
24      as a potential treatment option;”.

25           (2) in paragraph (5) to read as follows:

1           “(5) establish a program for the recruitment of  
2 new bone marrow donors that includes—

3           “(A) the priority to increase minority po-  
4 tential marrow donors for which there is a  
5 greater degree of marrow donor shortage than  
6 that of the general population; and

7           “(B) the compilation and distribution of  
8 informational materials to educate and update  
9 potential donors;”;

10          (3) by redesignating paragraphs (6) and (7) as  
11 paragraphs (8) and (9), respectively; and

12          (4) by inserting after paragraph (5), the follow-  
13 ing new paragraphs:

14           “(6) annually update the Donor Registry to ac-  
15 count for changes in potential donor status;

16           “(7) not later than 1 year after the date on  
17 which the ‘Bone Marrow Program Inspection’ (here-  
18 after referred to in this part as the ‘Inspection’) that  
19 is being conducted by the Office of the Inspector  
20 General on the date of enactment of this paragraph  
21 is completed, in consultation with the Secretary, and  
22 based on the findings and recommendations of the  
23 Inspection, the marrow donor program shall develop,  
24 evaluate, and implement a plan to streamline and

1       make more efficient the relationship between the  
2       Donor Registry and donor centers;”.

3       (c) INFORMATION AND EDUCATION PROGRAM.—Sec-  
4       tion 379 of such Act (42 U.S.C. 274k) is amended—

5           (1) by redesignating subsection (j) as sub-  
6       section (k); and

7           (2) by inserting after subsection (i), the follow-  
8       ing new subsection:

9       “(j) INFORMATION AND EDUCATION PROGRAM.—

10           “(1) IN GENERAL.—The Secretary may enter  
11       into contracts with, public or nonprofit private enti-  
12       ties for the purpose of increasing unrelated  
13       allogeneic marrow transplants, by enabling such en-  
14       tities to—

15           “(A) plan and conduct programs to provide  
16       information and education to the professional  
17       health care community on the availability of un-  
18       related allogeneic marrow transplants as a po-  
19       tential treatment option;

20           “(B) plan and conduct programs to pro-  
21       vide information and education to the public on  
22       the need for donations of bone marrow;

23           “(C) train individuals in requesting bone  
24       marrow donations; and



1           “(D) recruit, test and enroll marrow do-  
 2           nors with the priority being minorities for which  
 3           there is a greater degree of marrow donor  
 4           shortage than that of the general population.

5           “(2) PRIORITIES.—In awarding contracts under  
 6           paragraph (1), the Secretary shall give priority to  
 7           carrying out the purposes described in such para-  
 8           graph with respect to minority populations.”.

9           (d) PATIENT ADVOCACY AND CASE MANAGEMENT.—

10           (1) IN GENERAL.—Section 379 of such Act (42  
 11           U.S.C. 274k), as amended by subsection (e), is fur-  
 12           ther amended—

13           (A) by redesignating subsection (k) as sub-  
 14           section (l); and

15           (B) by inserting after subsection (j), the  
 16           following new subsection:

17           “(k) PATIENT ADVOCACY AND CASE MANAGE-  
 18           MENT.—

19           “(1) ESTABLISHMENT.—The Donor Registry  
 20           shall establish and maintain an office of patient ad-  
 21           vocacy and case management that meets the require-  
 22           ments of this subsection.

23           “(2) FUNCTIONS.—The office established under  
 24           paragraph (1) shall—

1           “(A) be headed by a director who shall  
2           serve as an advocate on behalf of—

3                   “(i) individuals who are registered  
4                   with the Donor Registry to search for a  
5                   biologically unrelated bone marrow donor;

6                   “(ii) the physicians involved; and

7                   “(iii) individuals who are included in  
8                   the Donor Registry as potential marrow  
9                   donors.

10           “(B) establish and maintain a system for  
11           patient advocacy that directly assists patients,  
12           their families, and their physicians in a search  
13           for an unrelated donor;

14           “(C) provide individual case management  
15           services to directly assist individuals and physi-  
16           cians referred to in subparagraph (A), includ-  
17           ing—

18                   “(i) individualized case assessment  
19                   and tracking of preliminary search through  
20                   activation (including when the search proe-  
21                   cess is interrupted or discontinued);

22                   “(ii) informing individuals and physi-  
23                   cians on regular intervals of progress made  
24                   in searching for appropriate donors; and

1                   “(iii) identifying and resolving individ-  
2                   ual search problems or concerns;

3                   “(D) collect and analyze data concerning  
4                   the number and percentage of individuals pro-  
5                   ceeding from preliminary to formal search, for-  
6                   mal search to transplantation, the number and  
7                   percentage of patients unable to complete the  
8                   search process, and the comparative costs in-  
9                   curred by patients prior to transplant;

10                   “(E) survey patients to evaluate how well  
11                   such patients are being served and make rec-  
12                   ommendations for streamlining the search pro-  
13                   cess; and

14                   “(F) provide individual case management  
15                   services to individual marrow donors.

16                   “(3) EVALUATION.—

17                   “(A) IN GENERAL.—The Secretary shall  
18                   evaluate the system established under para-  
19                   graph (1) and make recommendations concern-  
20                   ing the success or failure of such system in im-  
21                   proving patient satisfaction, and any impact the  
22                   system has had on assisting individuals in pro-  
23                   ceeding to transplant.

24                   “(B) REPORT.—Not later than April 1,  
25                   1996, the Secretary shall prepare and make

1 available a report concerning the evaluation  
 2 conducted under subparagraph (A), including  
 3 the recommendations developed under such sub-  
 4 paragraph.”.

5 (2) DONOR REGISTRY FUNCTIONS.—Section  
 6 379(b)(2) of such Act (42 U.S.C. 274k(b)(2)) is  
 7 amended by striking “establish” and all that follows  
 8 through “directly assists” and inserting “integrate  
 9 the activities of the patient advocacy and case man-  
 10 agement office established under subsection (k) with  
 11 the remaining Donor Registry functions by making  
 12 available information on (A) the resources available  
 13 through the Donor Registry Program, (B) the com-  
 14 parative costs incurred by patients prior to trans-  
 15 plant, and (C) the marrow donor registries that  
 16 meet the standards described in paragraphs (3) and  
 17 (4) of subsection (e), to assist”.

18 (c) STUDY AND REPORTS.—Section 379A of such Act  
 19 (42 U.S.C. 274l) is amended to read as follows:

20 **“SEC. 379A. STUDIES, EVALUATIONS AND REPORTS.**

21 **“(a) EVALUATION BY THE INSTITUTE OF MEDI-**  
 22 **CINE.—**

23 **“(1) IN GENERAL.—**The Secretary shall enter  
 24 into a contract with a public or nonprofit private en-  
 25 tity to conduct a study and evaluation of—

1           “(A) the role of a national bone marrow  
2 transplant program supported by the Federal  
3 Government in facilitating the maximum num-  
4 ber of unrelated marrow donor transplants; and

5           “(B) other possible clinical or scientific  
6 uses of the potential donor pool or accompany-  
7 ing information maintained by the Donor Reg-  
8 istry or the unrelated marrow donor scientific  
9 registry.

10          “(2) INSTITUTE OF MEDICINE.—The Secretary  
11 shall request the Institute of Medicine of the Na-  
12 tional Academy of Sciences to enter into the contract  
13 under paragraph (1) to conduct the study and eval-  
14 uation described in such paragraph. If the Institute  
15 declines to conduct the study and evaluation under  
16 such paragraph, the Secretary shall carry out such  
17 activities through another public or nonprofit private  
18 entity.

19          “(3) REPORT.—Not later than 2 years after the  
20 date of enactment of this section, the Institute of  
21 Medicine (or other entity as the case may be) shall  
22 complete the study required under paragraph (1)  
23 and prepare and submit to the Committee on Labor  
24 and Human Resources of the Senate, a report de-  
25 scribing the findings made as a result of the study.

1 “(b) BONE MARROW CONSOLIDATION.—

2 “(1) IN GENERAL.—The Secretary shall con-  
3 duct—

4 “(A) an evaluation of the feasibility of in-  
5 tegrating or consolidating all federally funded  
6 bone marrow transplantation scientific reg-  
7 istries, regardless of the type of marrow recon-  
8 stitution utilized; and

9 “(B) an evaluation of all federally funded  
10 bone marrow transplantation research to be  
11 conducted under the direction and administra-  
12 tion of the peer review system of the National  
13 Institutes of Health.

14 “(2) REPORT.—Not later than 1 year after the  
15 date of enactment of this section, the Secretary shall  
16 prepare and submit to the Committee on Labor and  
17 Human Resources of the Senate a report concerning  
18 the evaluations conducted under paragraph (1).

19 “(3) DEFINITION.—As used in paragraph (1),  
20 the term ‘marrow reconstitution’ shall encompass all  
21 sources of hematopoietic cells including marrow  
22 (autologous, related or unrelated allogeneic,  
23 syngeneic), autologous marrow, allogeneic marrow  
24 (biologically related or unrelated), umbilical cord

1 blood cells, peripheral blood progenitor cells, or other  
2 approaches that may be utilized.”.

3 (f) BONE MARROW TRANSPLANTATION SCIENTIFIC  
4 REGISTRY.—Part I of title III of such Act (42 U.S.C.  
5 274k et seq.) is amended by adding at the end thereof  
6 the following new section:

7 **“SEC. 379B. BONE MARROW SCIENTIFIC REGISTRY.**

8 “(a) ESTABLISHMENT.—The Secretary, acting  
9 through the Donor Registry, shall establish and maintain  
10 a bone marrow scientific registry of all recipients of bio-  
11 logic unrelated allogeneic marrow donors.

12 “(b) INFORMATION.—The bone marrow transplan-  
13 tation scientific registry established under subsection (a)  
14 shall include information with respect to patients who have  
15 received biologic unrelated allogeneic marrow transplant,  
16 transplant procedures, pretransplant and transplant costs,  
17 and other information the Secretary determines to be nec-  
18 essary to conduct an ongoing evaluation of the scientific  
19 and clinic status of unrelated allogeneic marrow transplan-  
20 tation.

21 “(c) REPORT.—The Donor Registry shall submit to  
22 the Secretary on an annual basis a report using data col-  
23 lected and maintained by the bone marrow transplantation  
24 scientific registry established under subsection (a) con-  
25 cerning patient outcomes with respect to each transplant

1 center and the pretransplant comparative costs involved  
2 at such transplant centers.”.

3 (g) **AUTHORIZATION OF APPROPRIATIONS.**—Part I of  
4 title III of such Act (42 U.S.C. 274k et seq.) as amended  
5 by subsection (f), is further amended by adding at the end  
6 thereof the following new section:

7 **“SEC. 379C. AUTHORIZATION OF APPROPRIATIONS.**

8 “There are authorized to be appropriated to carry out  
9 section 379, \$13,500,000 for fiscal year 1997,  
10 \$12,150,000 for fiscal year 1998, and such sums as may  
11 be necessary for fiscal year 1999.”.

12 **SECTION 1. SHORT TITLE.**

13 *This Act may be cited as the “Organ and Bone Mar-*  
14 *row Transplant Program Reauthorization Act of 1995”.*

15 ***TITLE I—SOLID-ORGAN***  
16 ***TRANSPLANT PROGRAM***

17 **SEC. 101. SHORT TITLE.**

18 *This title may be cited as the “Solid-Organ Trans-*  
19 *plant Program Reauthorization Act of 1995”.*

20 **SEC. 102. ORGAN PROCUREMENT ORGANIZATIONS.**

21 (a) **IN GENERAL.**—Subsection (a) of section 371 of the  
22 *Public Health Service Act (42 U.S.C. 273(a)) is amended*  
23 *to read as follows:*

24 “(a)(1) *The Secretary may enter into cooperative*  
25 *agreements and contracts with qualified organ procurement*



1 *organizations described in subsection (b) and other public*  
2 *or nonprofit private entities for the purpose of increasing*  
3 *organ donation through approaches such as—*

4           “(A) *the planning and conducting of programs*  
5 *to provide information and education to the public on*  
6 *the need for organ donations;*

7           “(B) *the training of individuals in requesting*  
8 *such donations;*

9           “(C) *the provision of technical assistance to*  
10 *organ procurement organizations and other entities*  
11 *that can contribute to organ donation;*

12           “(D) *the performance of research and the per-*  
13 *formance of demonstration programs by organ pro-*  
14 *curement organizations and other entities that may*  
15 *increase organ donation;*

16           “(E) *the voluntary consolidation of organ pro-*  
17 *curement organizations and tissue banks; or*

18           “(F) *increasing organ donation and access to*  
19 *transplantation with respect to populations for which*  
20 *there is a greater degree of organ shortages relative to*  
21 *the general population.*

22           “(2)(A) *In entering into cooperative agreements and*  
23 *contracts under subparagraphs (A) and (B) of paragraph*  
24 *(1), the Secretary shall give priority to increasing dona-*

1 *tions and improving consent rates for the purpose described*  
 2 *in such paragraph.*

3       “(B) *In entering into cooperative agreements and con-*  
 4 *tracts under paragraph (1)(C), the Secretary shall give pri-*  
 5 *ority to carrying out the purpose described in such para-*  
 6 *graph with respect to increasing donations from both organ-*  
 7 *procurement organizations and hospitals.”.*

8       (b) *QUALIFIED ORGAN PROCUREMENT ORGANIZA-*  
 9 *TIONS.—Section 371(b) of such Act (42 U.S.C. 273(b)) is*  
 10 *amended—*

11           (1) *in paragraph (1)—*

12                   (A) *in the matter preceding subparagraph*

13                   (A)—

14                           (i) *by striking “for which grants may*  
 15 *be made under subsection (a)” and insert-*  
 16 *ing “described in this section”; and*

17                           (ii) *by striking “paragraph (2)” and*  
 18 *inserting “Paragraph (3)”;*

19                   (B) *by realigning the margin of subpara-*  
 20 *graph (E) so as to align with the margin of sub-*  
 21 *paragraph (D); and*

22                   (C) *in subparagraph (G)—*

23                           (i) *in the matter preceding clause (i),*  
 24 *by striking “directors or an advisory*  
 25 *board” and inserting “directors (or an ad-*

1 *visory board, in the case of a hospital-based*  
2 *organ procurement organization established*  
3 *prior to September 1, 1993)”; and*

4 *(ii) in clause (i)—*

5 *(I) by striking “composed of” in*  
6 *the matter preceding subclause (I) and*  
7 *inserting “composed of a reasonable*  
8 *balance of”;*

9 *(II) by inserting before the comma*  
10 *in subclause (II) the following: “, in-*  
11 *cluding individuals who have received*  
12 *a transplant of an organ (or trans-*  
13 *plant candidates), and individuals who*  
14 *are part of the family of an individual*  
15 *who has donated or received an organ*  
16 *or who is a transplant candidate”;*

17 *(III) by striking subclause (IV)*  
18 *and inserting the following new sub-*  
19 *clause:*

20 *“(IV) physicians or other health care*  
21 *professionals with knowledge and skill in*  
22 *the field of neurology, emergency medicine,*  
23 *or trauma surgery”; and*

24 *(IV) in subclause (V), by striking*  
25 *“a member” and all that follows*

1                   *through the comma and insert the fol-*  
2                   *lowing: “a member who is a surgeon*  
3                   *or physician who has privileges to*  
4                   *practice in such centers and who is ac-*  
5                   *tively and directly involved in caring*  
6                   *for transplant patients,”;*

7                   (2) *by striking paragraph (2);*

8                   (3) *by redesignating paragraph (3) as para-*  
9                   *graph (2);*

10                  (4) *in paragraph (2) (as so redesignated)—*

11                   (A) *in subparagraph (A)—*

12                   (i) *by striking “a substantial major-*  
13                   *ity” and inserting “all”;*

14                   (ii) *by striking “donations,” and in-*  
15                   *serting “donation, unless they have been*  
16                   *previously granted by the Secretary a waiv-*  
17                   *er from paragraph (1)(A) or have waivers*  
18                   *pending under section 1138 of the Social*  
19                   *Security Act”;* and

20                   (iii) *by adding at the end thereof the*  
21                   *following: “except that the Secretary may*  
22                   *waive the requirements of this subpara-*  
23                   *graph upon the request of the organ pro-*  
24                   *curement organization if the Secretary de-*

1                   *termines that such an agreement would not*  
2                   *be helpful in promoting organ donation,”;*

3                   *(B) by redesignating subparagraphs (B)*  
4                   *through (K) as subparagraphs (D) through (M),*  
5                   *respectively,*

6                   *(C) by inserting after subparagraph (A) the*  
7                   *following new subparagraphs:*

8                   *“(B) conduct and participate in systematic ef-*  
9                   *forts, including public education, to increase the num-*  
10                   *ber of potential donors, including populations for*  
11                   *which there is a greater degree of organ shortage than*  
12                   *that of the general population,*

13                   *“(C) be a member of and abide by the rules and*  
14                   *requirements of the Organ Procurement and Trans-*  
15                   *plantation Network (referred to in this part as the*  
16                   *‘Network’) established under section 372,”;*

17                   *(D) by inserting before the comma in sub-*  
18                   *paragraph (G) (as so redesignated) the following:*

19                   *“, which system shall, at a minimum, allocate*  
20                   *each type of organ on the basis of—*

21                   *“(i) a single list encompassing the entire*  
22                   *service area;*

23                   *“(ii) a list that encompasses at least an en-*  
24                   *tire State;*

1           “(iii) a list that encompasses an approved  
2           alternative local unit (as defined in paragraph  
3           (3)) that is approved by the Network and the  
4           Secretary, or

5           “(iv) a list that encompasses another alloca-  
6           tion system which has been approved by the Net-  
7           work and the Secretary,  
8           of individuals who have been medically referred to a  
9           transplant center in the service area of the organiza-  
10          tion in order to receive a transplant of the type of  
11          organ with respect to which the list is maintained  
12          and had been placed on an organ specific waiting  
13          list;”;

14           (E) by inserting before the comma in sub-  
15          paragraph (I) (as so redesignated) the following:  
16          “and work with local transplant centers to en-  
17          sure that such centers are actively involved with  
18          organ donation efforts”; and

19           (F) by inserting after “evaluate annually”  
20          in subparagraph (L) (as so redesignated) the fol-  
21          lowing “and submit data to the Network contrac-  
22          tor on” the effectiveness of the organization,”;  
23          and

24           (5) by adding at the end thereof the following  
25          new paragraph:

1       “(3)(A) *As used in paragraph (2)(G), the term ‘alter-*  
2 *native local unit’ means—*

3               “(i) *a unit composed of two or more organ pro-*  
4 *curement organizations; or*

5               “(ii) *a subdivision of an organ procurement or-*  
6 *ganization that operates as a distinct procurement*  
7 *and distribution unit as a result of special geo-*  
8 *graphic, rural, or population concerns but that is not*  
9 *composed of any subunit of a metropolitan statistical*  
10 *area.*

11       “(B) *The Network shall make recommendations to the*  
12 *Secretary concerning the approval or denial of alternative*  
13 *local units. The Network shall assess whether the alternative*  
14 *local units will better promote organ donation and the equi-*  
15 *table allocation of organs.*

16       “(C) *The Secretary shall approve or deny any alter-*  
17 *native local unit designation recommended by the Network.*  
18 *The Secretary shall have 60 days, beginning on the date*  
19 *on which the application is submitted to the Secretary, to*  
20 *approve or deny the recommendations of the Network under*  
21 *subparagraph (B) with respect to the application of the al-*  
22 *ternative local unit.”.*

23       (c) *AFFECT OF AMENDMENTS.—The amendments*  
24 *made by subsection (b) shall not be construed to affect the*

1 *provisions of section 1138(a) of the Social Security Act (42*  
 2 *U.S.C. 1320b-8(a)).*

3 *(d) EFFECTIVE DATE.—The amendments made by*  
 4 *subsection (b) shall apply to organ procurement organiza-*  
 5 *tions and the Organ Procurement and Transplantation*  
 6 *Network beginning January 1, 1996.*

7 **SEC. 103. ORGAN PROCUREMENT AND TRANSPLANTATION**  
 8 **NETWORK.**

9 *(a) OPERATION.—Subsection (a) of section 372 of the*  
 10 *Public Health Service Act (42 U.S.C. 274(a)) is amended*  
 11 *to read as follows:*

12 *“(a)(1) Congress finds that—*

13 *“(A) it is in the public interest to maintain and*  
 14 *improve a durable system for promoting and support-*  
 15 *ing a central network to assist organ procurement or-*  
 16 *ganizations in the nationwide distribution of organs*  
 17 *among transplant patients;*

18 *“(B) it is desirable to continue the partnership*  
 19 *between public and private enterprise, by continuing*  
 20 *to provide Federal Government oversight and assist-*  
 21 *ance for services performed by the Network; and*

22 *“(C) the Federal Government should actively*  
 23 *oversee Network activities to ensure that the policies*  
 24 *and procedures of the Network for serving patient and*  
 25 *donor families and procuring and distributing organs*



1        *are fair, efficient and in compliance with all applica-*  
2        *ble legal rules and standards; however, the initiative*  
3        *and primary responsibility for establishing medical*  
4        *criteria and standards for organ procurement and*  
5        *transplantation stills resides with the Network.*

6        *“(2) The Secretary shall provide by contract for the*  
7        *operation of the Network which shall meet the requirements*  
8        *of subsection (b).*

9        *“(3) The Network shall be recognized as a private en-*  
10       *tity that has an expertise in organ procurement and trans-*  
11       *plantation with the primary purposes of encouraging organ*  
12       *donation, maintaining a ‘wait list’, and operating and*  
13       *monitoring an equitable and effective system for allocating*  
14       *organs to transplant recipients, and shall report to the Sec-*  
15       *retary instances of continuing noncompliance with policies*  
16       *(or when promulgated, rules) and requirements of the Net-*  
17       *work.*

18       *“(4) The Network may assess a fee (to be known as*  
19       *the ‘patient registration fee’), to be collected by the contrac-*  
20       *tor for listing each potential transplant recipient on its na-*  
21       *tional organ matching system, in an amount which is rea-*  
22       *sonable and customary and determined by the Network and*  
23       *approved as such by the Secretary. The patient registration*  
24       *fee shall be calculated so as to be sufficient to cover the Net-*  
25       *work’s reasonable costs of operation in accordance with this*

1 *section. The Secretary shall have 60 days, beginning on the*  
2 *date on which the written application justifying the pro-*  
3 *posed fee as reasonable is submitted to the Secretary, to pro-*  
4 *vide the Network with a written determination and ration-*  
5 *ale for such determination that the proposed increase is not*  
6 *reasonable and customary and that the Secretary dis-*  
7 *approves the recommendation of the Network under this*  
8 *paragraph with respect to the change in fee for listing each*  
9 *potential transplant recipient.*

10       *“(5) Any increase in the patient registration fee shall*  
11 *be limited to an increase that is reasonably required as a*  
12 *result of—*

13             *“(A) increases in the level or cost of contract*  
14 *tasks and other activities related to organ procure-*  
15 *ment and transplantation; or*

16             *“(B) decreases in expected revenue from patient*  
17 *registration fees available to the contractor.*

18 *The patient registration fees shall not be increased more*  
19 *than once during each year.*

20       *“(6) All fees collected by the Network contractor under*  
21 *paragraph (4) shall be available to the Network without fis-*  
22 *cal year limitation. The contract with the Network contrac-*  
23 *tor shall provide that expenditures of such funds (including*  
24 *patient registration fees collected by the contractor and or*  
25 *contract funds) are subject to annual audit under the provi-*

1 sions of the Office of Management and Budget Circular No.  
2 A-133 entitled 'Audits of Institutions of Higher Learning  
3 and Other Nonprofit Institutions'. A report concerning the  
4 audit and recommendations regarding expenditures shall be  
5 submitted to the Network, the contractor, and the Secretary.

6       “(7) The Secretary may institute and collect a data  
7 management fee from transplant hospitals and organ pro-  
8 curement organizations. Such fees shall be directed to and  
9 shall be sufficient to cover—

10               “(A) the costs of the operation and administra-  
11 tion of the Scientific Registry in accordance with the  
12 contract under section 373; and

13               “(B) the costs of contracts and cooperative agree-  
14 ments to support efforts to increase organ donation  
15 under section 371.

16 Such data management fee shall be set annually by the Net-  
17 work in an amount determined by the Network, in consulta-  
18 tion with the Secretary, and approved by the Secretary.  
19 Such data management fee shall be calculated based on the  
20 number of transplants performed or facilitated by each  
21 transplant hospital or center, or organ procurement organi-  
22 zation. The per transplant data management fee shall be  
23 divided so that the patient specific transplant center will  
24 pay 80 percent and the procuring organ procurement orga-  
25 nization will pay 20 percent of the per transplant data

1 *management fee. Such fees shall be available to the Sec-*  
 2 *retary and the contractor operating the Scientific Registry*  
 3 *without fiscal year limitation. The expenditure (including*  
 4 *fees or contract funds) of such fees by the contractor shall*  
 5 *be subject to an annual independent audit (performed by*  
 6 *the Secretary or an authorized auditor at the discretion of*  
 7 *the Secretary) and reported along with recommendations*  
 8 *regarding such expenditures, to the Network, the contractor*  
 9 *and the Secretary.*

10       “(8) *The Secretary and the Comptroller General shall*  
 11 *have access to all data collected by the contractor or contrac-*  
 12 *tors in carrying out its responsibilities under the contract*  
 13 *under this section and section 373.”.*

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

16               (1) *in paragraph (1)(B)—*

17                       (A) *in clause (i)—*

18                               (i) *by striking “(including organiza-*  
 19 *tions that have received grants under sec-*  
 20 *tion 371)”;* and

21                               (ii) *by striking “; and” at the end*  
 22 *thereof and inserting “(including both indi-*  
 23 *viduals who have received a transplant of*  
 24 *an organ (or transplant candidates), indi-*  
 25 *viduals who are part of the family of indi-*

1            *viduals who have donated or received an*  
2            *organ, the number of whom shall make up*  
3            *a reasonable portion of the total number of*  
4            *board members), and the Division of Organ*  
5            *Transplantation of the Bureau of Health*  
6            *Resources Development (the Health Re-*  
7            *sources and Services Administration) shall*  
8            *be represented at all meetings except for*  
9            *those pertaining to the Network contractor's*  
10           *internal business;”;*

11           *(B) in clause (ii)—*

12                    *(i) by inserting “including a patient*  
13                    *affairs committee and a minority affairs*  
14                    *committee” after “committees;” and*

15                    *(ii) by striking the period; and*

16                    *(C) by adding at the end thereof the follow-*  
17                    *ing new clauses:*

18                    *“(iii) that shall include representation by a*  
19                    *member of the Division of Organ Transplan-*  
20                    *tation of the Bureau of Health Resources Devel-*  
21                    *opment (the Health Resources and Services Ad-*  
22                    *ministration) as a representative at all meetings*  
23                    *(except for those portions of committee meetings*  
24                    *pertaining to the Network contractor's internal*  
25                    *business) of all committees (including the execu-*

1           *tive committee, finance committee, nominating*  
2           *committee, and membership and professional*  
3           *standards committee) under clause (ii);*

4           *“(iv) that may include a member from an*  
5           *organ procurement organization on all commit-*  
6           *tees under clause (ii); and*

7           *“(v) that may include physicians or other*  
8           *health care professionals with knowledge and*  
9           *skill in the field of neurology, emergency medi-*  
10          *cine, and trauma surgery on all committees*  
11          *under clause (ii).”;* and

12          *(2) in paragraph (2)—*

13            *(A) in subparagraph (A)—*

14            *(i) in the matter preceding clause (i),*  
15            *by striking “or through regional centers”*  
16            *and inserting “and at each Organ Procure-*  
17            *ment Organization”;* and

18            *(ii) by striking clause (i) and inserting*  
19            *the following new clause:*

20            *“(i) with respect to each type of transplant,*  
21            *a national list of individuals who have been*  
22            *medically referred to receive a transplant of the*  
23            *type of organs with respect to which the list is*  
24            *maintained (which list shall include the names*

1           *of all individuals included on lists in effect*  
2           *under section 371(b)(2)(G), and”;*

3           *(B) in subparagraph (B), by inserting “,*  
4           *including requirements under section 371(b),”*  
5           *after “membership criteria”;*

6           *(C) by redesignating subparagraphs (E)*  
7           *through (L), as subparagraphs (F) through (M),*  
8           *respectively;*

9           *(D) by inserting after subparagraph (D),*  
10          *the following new subparagraph:*

11          *“(E) assist and monitor organ procurement or-*  
12          *ganizations in the equitable distribution of organs*  
13          *among transplant patients,”;*

14          *(E) in subparagraph (K) (as so redesign-*  
15          *ated), by striking “and” at the end thereof;*

16          *(F) in subparagraph (L) (as so redesign-*  
17          *ated), by striking the period and inserting “,*  
18          *including making recommendations to organ*  
19          *procurements organizations and the Secretary*  
20          *based on data submitted to the Network under*  
21          *section 371(b)(2)(L),”;*

22          *(G) in subparagraph (M) (as so redesign-*  
23          *ated)—*

24                  *(i) by striking “annual” and inserting*  
25                  *“biennial”;*

1                   (ii) by striking “the comparative costs  
2                   and”;

3                   (iii) by striking the period and insert-  
4                   ing the following: “, including survival in-  
5                   formation, waiting list information, and in-  
6                   formation pertaining to the qualifications  
7                   and experience of transplant surgeons and  
8                   physicians affiliated with the specific Net-  
9                   work programs,”; and

10                  (H) by adding at the end thereof the follow-  
11                  ing new subparagraphs:

12                  “(N) submit to the Secretary for approval a  
13                  written notice containing a justification, as reason-  
14                  able and customary, of any proposed increase in the  
15                  patient registration fees as maintained under sub-  
16                  paragraph (A)(i), such change to be considered as so  
17                  approved if the Secretary does not provide written no-  
18                  tification otherwise prior to the expiration of the 60-  
19                  day period beginning on the date on which the notice  
20                  of proposed change is submitted to the Secretary,

21                  “(O) make available to the Secretary such infor-  
22                  mation, books, and records regarding the Network as  
23                  the Secretary may require,

24                  “(P) submit to the Secretary, in a manner pre-  
25                  scribed by the Secretary, an annual report concerning



1       *the scientific and clinical status of organ donation*  
2       *and transplantation, and*

3               “(Q) *meet such other criteria regarding compli-*  
4       *ance with this part as the Secretary may establish.*”.

5       (c) *PROCEDURES.*—*Section 372(c) of the Public*  
6 *Health Service Act (42 U.S.C. 274(c)) is amended—*

7               (1) *in paragraph (1), by striking “and” at the*  
8       *end thereof;*

9               (2) *in paragraph (2), by striking the period and*  
10       *inserting a semicolon; and*

11              (3) *by adding at the end thereof the following*  
12       *new paragraphs:*

13              “(3) *working through and with, the Network con-*  
14       *tractor to define priorities; and*

15              “(4) *working through, working with, and direct-*  
16       *ing the Network contractor to respond to new emerg-*  
17       *ing issues and problems.*”.

18       (d) *EXPANSION OF ACCESS.*—*Section 372 of the Public*  
19 *Health Service Act (42 U.S.C. 274) is amended by adding*  
20 *at the end thereof the following new subsection:*

21              “(d) *EXPANSION OF ACCESS TO COMMITTEES AND*  
22 *BOARD OF DIRECTORS.*—*Not later than 1 year after the*  
23 *completion of the Institute of Medicine report required*  
24 *under section 377, the Network contractor, in consultation*  
25 *with the Network and the Secretary, shall present to the*

1 *Secretary and the appropriate committees of Congress, a*  
2 *plan to implement the study recommendations relating to*  
3 *the access of all interested constituencies and organizations*  
4 *to membership on the Network Board of Directors and all*  
5 *of its committees. Ensuring the reasonable mix of all popu-*  
6 *lations shall be a priority of the plan for implementation.”.*

7 *(e) REGULATIONS.—*

8 *(1) IN GENERAL.—Not later than the expiration*  
9 *of the 1-year period beginning on the date of enact-*  
10 *ment of this Act, the Secretary of Health and Human*  
11 *Services shall issue a final rule to establish the regu-*  
12 *lations for criteria under part H of title III of the*  
13 *Public Health Service Act (42 U.S.C. 273 et seq.).*

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 Network.*

18 *(3) FAILURE TO ISSUE REGULATIONS BY DATE*  
19 *CERTAIN.—If the Secretary fails to issue a final rule*  
20 *under paragraph (1) prior to the expiration of the pe-*  
21 *riod referred to in such paragraph, the Secretary*  
22 *shall, not later than 30 days after the expiration of*  
23 *such period, prepare and submit to the appropriate*  
24 *committees of Congress a report describing the reasons*  
25 *why the Secretary is not in compliance with para-*

1        *graph (1) and the plans that will be implemented to*  
 2        *provide for the issuance of the final rule under such*  
 3        *paragraph.*

4        **SEC. 104. TERMS AND CONDITIONS OF CONTRACTS.**

5        *Section 374 of the Public Health Service Act (42*  
 6        *U.S.C. 274b) is amended—*

7                *(1) in subsection (b)(2), by striking “two years”*  
 8                *and inserting “(three years)”;*

9                *(2) in subsection (c)—*

10                        *(A) by redesignating paragraph (1) and (2)*  
 11                        *as paragraphs (2) and (3), respectively; and*

12                        *(B) by inserting before paragraph (2) (as so*  
 13                        *redesignated) the following new paragraph:*

14                *“(1) The Secretary shall annually withhold not to ex-*  
 15        *ceed \$250,000 or 10 percent of the amount of the data man-*  
 16        *agement fees collected under section 372 (whichever is great-*  
 17        *er) to be used to fund contracts as described in section*  
 18        *371.”;*

19                *(3) by redesignating subsection (d) as subsection*  
 20        *(e); and*

21                *(4) by adding at the end thereof the following*  
 22        *new subsection:*

23                *“(d) No contract in excess of \$25,000 may be made*  
 24        *under this part using funds withheld under subsection*  
 25        *(c)(1) unless an application for such contract has been sub-*

1 *mited to the Secretary, recommended by the Network and*  
2 *approved by the Secretary. Such an application shall be*  
3 *in such form and be submitted in such a manner as the*  
4 *Secretary shall prescribe.”.*

5 **SEC. 105. ADMINISTRATION.**

6 *Section 375 of the Public Health Service Act (42*  
7 *U.S.C. 274c) is amended—*

8 *(1) in section 375 (42 U.S.C. 274c), by inserting*  
9 *before the dash the following: “oversee the Network, the*  
10 *Scientific Registry and to”;*

11 *(2) in paragraph (3)—*

12 *(A) by striking “in the health care system”;*

13 *and*

14 *(B) by striking “and” at the end thereof;*

15 *(3) in paragraph (4), by striking the period and*  
16 *inserting “; and”; and*

17 *(4) by adding at the end thereof the following*  
18 *new paragraph:*

19 *“(5) through contract, prepare a triennial organ*  
20 *procurement organization specific data report (the*  
21 *initial report to be completed not later than 18*  
22 *months after the date of enactment of this paragraph)*  
23 *that includes—*

24 *“(A) data concerning the effectiveness of*  
25 *each organ procurement organization in acquir-*

1            *ing potentially available organs, particularly*  
 2            *among minority populations;*

3            *“(B) data concerning the variation of pro-*  
 4            *curement across hospitals within the organ pro-*  
 5            *curement organization region;*

6            *“(C) a plan to increase procurement, par-*  
 7            *ticularly among populations for which there is a*  
 8            *greater degree of organ shortages relative to the*  
 9            *general population; and*

10           *“(D) a plan to increase procurement at hos-*  
 11           *pitals with low rates of procurement.”.*

12    **SEC. 106. STUDY AND REPORT.**

13           *Section 377 of the Public Health Service Act (42*  
 14           *U.S.C. 274f) is amended to read as follows:*

15    **“SEC. 377. STUDY AND REPORT.**

16           *“(a) EVALUATION BY THE INSTITUTE OF MEDICINE.—*

17           *“(1) IN GENERAL.—The Secretary shall enter*  
 18           *into a contract with a public or nonprofit private en-*  
 19           *tity to conduct a study and evaluation of—*

20           *“(A) the role of and the impact of the Fed-*  
 21           *eral Government in the oversight and support of*  
 22           *solid-organ transplantation, the Network (which*  
 23           *on the date of enactment of this section carries*  
 24           *out its functions by government contract) and*

1           *the solid organ transplantation scientific reg-*  
2           *istry; and*

3           “(B) *the access of all interested constitu-*  
4           *encies and organizations to membership on the*  
5           *Network board of directors and all Network com-*  
6           *mittees;*

7           “(2) *INSTITUTE OF MEDICINE.—The Secretary*  
8           *shall request the Institute of Medicine of the National*  
9           *Academy of Sciences to enter into the contract under*  
10          *paragraph (1) to conduct the study and evaluation*  
11          *described in such paragraph. If the Institute declines*  
12          *to conduct the study and evaluation under such para-*  
13          *graph, the Secretary shall carry out such activities*  
14          *through another public or nonprofit private entity.*

15          “(b) *REPORT.—Not later than 2 years after the date*  
16          *of enactment of this section, the Institute of Medicine (or*  
17          *other entity as the case may be) shall complete the study*  
18          *required under subsection (a)(1) and prepare and submit*  
19          *to the Committee on Labor and Human Resources of the*  
20          *Senate, a report describing the findings made as a result*  
21          *of the study.”.*

22          **SEC. 107. GENERAL PROVISIONS.**

23          “(a) *CONTRACTS.—Section 374 of the Public Health*  
24          *Service Act (42 U.S.C. 274b) is amended—*

1           (1) *in the section heading, by striking*  
2           “GRANTS AND”;

3           (2) *in subsection (a), by striking “grant may be*  
4           *made under this part or contract” and inserting*  
5           *“contract may be”;*

6           (3) *in subsection (b)—*

7           (A) *in paragraph (1)—*

8           (i) *by striking “grant” and inserting*  
9           *“contract”; and*

10          (ii) *by striking “and may not exceed*  
11          *\$100,000”;*

12          (B) *by striking paragraph (2);*

13          (C) *by redesignating paragraph (3) as*  
14          *paragraph (2); and*

15          (D) *in paragraph (2) (as so redesignated)—*

16          (i) *by striking “Grants or contracts”*  
17          *and inserting “Contracts”; and*

18          (ii) *by striking “371(a)(3)” and insert-*  
19          *ing “371(a)(2)”;*

20          (4) *in subsection (c)—*

21          (A) *by striking “grant or” each place that*  
22          *such appears; and*

23          (B) *in paragraph (1), by striking “grants*  
24          *and”;* and

1           (5) in subsection (d)(2), by striking “and for  
2           purposes of section 373, such term includes bone mar-  
3           row”.

4           (b) *REPEAL.*—Sections 376 and 378 of the Public  
5           Health Service Act (42 U.S.C. 274d and 274g) are repealed.

6           **SEC. 108. AUTHORIZATION OF APPROPRIATION.**

7           Part H of title III of the Public Health Service Act  
8           (42 U.S.C. 273 et seq.) is amended by adding at the end  
9           thereof the following new section:

10          **“SEC. 378. AUTHORIZATION OF APPROPRIATIONS.**

11           *“There are authorized to be appropriated to carry out*  
12          *sections 371, 372, 375 and 377, \$1,950,000 for fiscal year*  
13          *1997, and \$1,100,000 for fiscal year 1998, and to carry*  
14          *out section 371, \$250,000 for each of the fiscal years 1999*  
15          *through 2001.”.*

16          **SEC. 109. EFFECTIVE DATES.**

17           *The amendments made by this title shall become effec-*  
18          *tive on the date of enactment of this Act.*

19          **TITLE II—BONE MARROW DONOR**  
20    **PROGRAM**

21          **SEC. 201. SHORT TITLE.**

22           *This title may be cited as the “Bone Marrow Trans-*  
23          *plantation Program Reauthorization Act of 1995”.*



1 **SEC. 202. REAUTHORIZATION.**

2 (a) *ESTABLISHMENT OF DONOR REGISTRY.*—Section  
3 379(a) of the Public Health Service Act (42 U.S.C. 274k(a))  
4 is amended—

5 (1) by striking “‘Registry’” and inserting  
6 “‘Donor Registry’”;

7 (2) by inserting after the end parenthesis the fol-  
8 lowing: “the primary purpose of which shall be in-  
9 creasing unrelated donor marrow transplants,”; and

10 (3) by adding at the end thereof the following:  
11 “With respect to the board of directors—

12 “(1) each member of the board shall serve for a  
13 term of 2 years, and each such member may serve as  
14 many as three consecutive 2-year terms;

15 “(2) a member of the board may continue to  
16 serve after the expiration of the term of such member  
17 until a successor is appointed;

18 “(3) to ensure the continuity of the board, not  
19 more than one-third of the board shall be composed of  
20 members newly appointed each year;

21 “(4) all appointed and elected positions within  
22 committees established by the board shall be for 2-year  
23 periods;

24 “(5) the terms of approximately one-third of the  
25 members of each such committee will be subject each  
26 year to reappointment or replacement;

1           “(6) no individual shall serve more than three  
2 consecutive 2-year terms on any such committee; and

3           “(7) the board and committees shall be composed  
4 of a reasonable balance of representatives of donor  
5 centers, transplant centers, blood banks, marrow  
6 transplant recipients, individuals who are family  
7 members of an individual who has required, received,  
8 or is registered with the Donor Registry to become a  
9 recipient of a transplant from a biologically unrelated  
10 marrow donor, with nonvoting representatives from  
11 the Naval Medical Research and Development Com-  
12 mand and the Division of Organ Transplantation of  
13 the Bureau of Health Resources Development (of the  
14 Health Resources and Services Administration).”.

15           (b) *PROGRAM FOR UNRELATED MARROW TRANS-*  
16 *PLANTS.*—Section 379(b) of such Act (42 U.S.C. 274k(b))  
17 is amended—

18           (1) in paragraph (4) to read as follows:

19           “(4) provide information to physicians, other  
20 health care professionals, and the public regarding the  
21 availability of unrelated marrow transplantation as a  
22 potential treatment option;”;

23           (2) in paragraph (5) to read as follows:

24           “(5) establish a program for the recruitment of  
25 new bone marrow donors that includes—

1           “(A) the priority to increase potential mar-  
2           row donors for which there is a greater degree of  
3           marrow donor shortage than that of the general  
4           population; and

5           “(B) the compilation and distribution of in-  
6           formational materials to educate and update po-  
7           tential donors;”;

8           (3) by redesignating paragraphs (6) and (7) as  
9           paragraphs (8) and (9), respectively; and

10          (4) by inserting after paragraph (5), the follow-  
11          ing new paragraphs:

12           “(6) annually update the Donor Registry to ac-  
13          count for changes in potential donor status;

14           “(7) not later than 1 year after the date on  
15          which the ‘Bone Marrow Program Inspection’ (here-  
16          after referred to in this part as the ‘Inspection’) that  
17          is being conducted by the Office of the Inspector Gen-  
18          eral on the date of enactment of this paragraph is  
19          completed, in consultation with the Secretary, and  
20          based on the findings and recommendations of the In-  
21          spection, the marrow donor program shall develop,  
22          evaluate, and implement a plan to streamline and  
23          make more efficient the relationship between the  
24          Donor Registry and donor centers;”.

1           (c) *INFORMATION AND EDUCATION PROGRAM.*—Sec-  
2 *tion 379 of such Act (42 U.S.C. 274k) is amended by strik-*  
3 *ing subsection (j), and inserting the following new sub-*  
4 *section:*

5           “(j) *INFORMATION AND EDUCATION PROGRAM.*—

6           “(1) *IN GENERAL.*—*The Secretary may enter*  
7 *into contracts with, public or nonprofit private enti-*  
8 *ties for the purpose of increasing unrelated allogeneic*  
9 *marrow transplants, by enabling such entities to—*

10                   “(A) *plan and conduct programs to provide*  
11 *information and education to the professional*  
12 *health care community on the availability of un-*  
13 *related allogeneic marrow transplants as a po-*  
14 *tential treatment option;*

15                   “(B) *plan and conduct programs to provide*  
16 *information and education to the public on the*  
17 *availability of unrelated donor marrow trans-*  
18 *plants and the need for donations of bone mar-*  
19 *row;*

20                   “(C) *train individuals in requesting bone*  
21 *marrow donations; and*

22                   “(D) *recruit, test and enroll marrow donors*  
23 *with the priority being groups for which there is*  
24 *a greater degree of marrow donor shortage than*  
25 *that of the general population.*

1           “(2) *PRIORITIES.*—*In awarding contracts under*  
 2           *paragraph (1), the Secretary shall give priority to*  
 3           *carrying out the purposes described in such para-*  
 4           *graph with respect to population groups with such*  
 5           *shortages.”.*

6           *(d) PATIENT ADVOCACY AND CASE MANAGEMENT.—*

7           *(1) IN GENERAL.—Section 379 of such Act (42*  
 8           *U.S.C. 274k), as amended by subsection (c), is*  
 9           *amended by adding at the end thereof the following*  
 10           *new subsection:*

11           “(k) *PATIENT ADVOCACY AND CASE MANAGEMENT.—*

12           *“(1) ESTABLISHMENT.—The Donor Registry*  
 13           *shall establish and maintain an office of patient ad-*  
 14           *vocacy and case management that meets the require-*  
 15           *ments of this subsection.*

16           “(2) *FUNCTIONS.—The office established under*  
 17           *paragraph (1) shall—*

18           *“(A) be headed by a director who shall serve*  
 19           *as an advocate on behalf of—*

20           *“(i) individuals who are registered*  
 21           *with the Donor Registry to search for a bio-*  
 22           *logically unrelated bone marrow donor;*

23           *“(ii) the physicians involved; and*

1           “(iii) individuals who are included in  
2           the Donor Registry as potential marrow do-  
3           nors.

4           “(B) establish and maintain a system for  
5           patient advocacy that directly assists patients,  
6           their families, and their physicians in a search  
7           for an unrelated donor;

8           “(C) provide individual case management  
9           services as appropriate to directly assist individ-  
10          uals and physicians referred to in subparagraph  
11          (A), including—

12           “(i) individualized case assessment and  
13           tracking of preliminary search through acti-  
14           vation (including when the search process is  
15           interrupted or discontinued);

16           “(ii) informing individuals and physi-  
17           cians on regular intervals of progress made  
18           in searching for appropriate donors; and

19           “(iii) identifying and resolving indi-  
20           vidual search problems or concerns;

21          “(D) collect and analyze data concerning  
22          the number and percentage of individuals pro-  
23          ceeding from preliminary to formal search, for-  
24          mal search to transplantation, the number and  
25          percentage of patients unable to complete the

1           *search process, and the comparative costs in-*  
2           *curring by patients prior to transplant;*

3           “(E) *survey patients to evaluate how well*  
4           *such patients are being served and make rec-*  
5           *ommendations for expediting the search process;*  
6           *and*

7           “(F) *provide individual case management*  
8           *services to individual marrow donors.*

9           “(3) *EVALUATION.—*

10           “(A) *IN GENERAL.—The Secretary shall*  
11           *evaluate the system established under paragraph*  
12           *(1) and make recommendations concerning the*  
13           *success or failure of such system in improving*  
14           *patient satisfaction, and any impact the system*  
15           *has had on assisting individuals in proceeding to*  
16           *transplant.*

17           “(B) *REPORT.—Not later than April 1,*  
18           *1996, the Secretary shall prepare and make*  
19           *available a report concerning the evaluation con-*  
20           *ducted under subparagraph (A), including the*  
21           *recommendations developed under such subpara-*  
22           *graph.”.*

23           “(2) *DONOR REGISTRY FUNCTIONS.—Section*  
24           *379(b)(2) of such Act (42 U.S.C. 274k(b)(2)) is*  
25           *amended by striking “establish” and all that follows*

1 through “directly assists” and inserting “integrate the  
 2 activities of the patient advocacy and case manage-  
 3 ment office established under subsection (k) with the  
 4 remaining Donor Registry functions by making  
 5 available information on (A) the resources available  
 6 through the Donor Registry Program, (B) the com-  
 7 parative costs incurred by patients prior to trans-  
 8 plant, and (C) the marrow donor registries that meet  
 9 the standards described in paragraphs (3) and (4) of  
 10 subsection (c), to assist”.

11 (e) *STUDY AND REPORTS.*—Section 379A of such Act  
 12 (42 U.S.C. 274l) is amended to read as follows:

13 **“SEC. 379A. STUDIES, EVALUATIONS AND REPORTS.**

14 “(a) *EVALUATION BY THE INSTITUTE OF MEDICINE.*—

15 “(1) *IN GENERAL.*—The Secretary shall enter  
 16 into a contract with a public or nonprofit private en-  
 17 tity to conduct a study and evaluation of—

18 “(A) the role of a national bone marrow  
 19 transplant program supported by the Federal  
 20 Government in facilitating the maximum num-  
 21 ber of unrelated marrow donor transplants; and

22 “(B) other possible clinical or scientific uses  
 23 of the potential donor pool or accompanying in-  
 24 formation maintained by the Donor Registry or  
 25 the unrelated marrow donor scientific registry.



1           “(2) *INSTITUTE OF MEDICINE.*—*The Secretary*  
2           *shall request the Institute of Medicine of the National*  
3           *Academy of Sciences to enter into the contract under*  
4           *paragraph (1) to conduct the study and evaluation*  
5           *described in such paragraph. If the Institute declines*  
6           *to conduct the study and evaluation under such para-*  
7           *graph, the Secretary shall carry out such activities*  
8           *through another public or nonprofit private entity.*

9           “(3) *REPORT.*—*Not later than 2 years after the*  
10          *date of enactment of this section, the Institute of Med-*  
11          *icine (or other entity as the case may be) shall com-*  
12          *plete the study required under paragraph (1) and*  
13          *prepare and submit to the Committee on Labor and*  
14          *Human Resources of the Senate, a report describing*  
15          *the findings made as a result of the study.*

16          “(b) *BONE MARROW CONSOLIDATION.*—

17                 “(1) *IN GENERAL.*—*The Secretary shall con-*  
18                 *duct—*

19                         “(A) *an evaluation of the feasibility of inte-*  
20                         *grating or consolidating all federally funded*  
21                         *bone marrow transplantation scientific reg-*  
22                         *istries, regardless of the type of marrow recon-*  
23                         *stitution utilized; and*

24                         “(B) *an evaluation of all federally funded*  
25                         *bone marrow transplantation research to be con-*

1           *ducted under the direction and administration of*  
 2           *the peer review system of the National Institutes*  
 3           *of Health.*

4           “(2) *REPORT.*—*Not later than 1 year after the*  
 5           *date of enactment of this section, the Secretary shall*  
 6           *prepare and submit to the Committee on Labor and*  
 7           *Human Resources of the Senate a report concerning*  
 8           *the evaluations conducted under paragraph (1).*

9           “(3) *DEFINITION.*—*As used in paragraph (1),*  
 10          *the term ‘marrow reconstitution’ shall encompass all*  
 11          *sources of hematopoietic cells including marrow*  
 12          *(autologous, related or unrelated allogeneic,*  
 13          *syngeneic), autologous marrow, allogeneic marrow*  
 14          *(biologically related or unrelated), umbilical cord*  
 15          *blood cells, peripheral blood progenitor cells, or other*  
 16          *approaches that may be utilized.”*

17          (f) *BONE MARROW TRANSPLANTATION SCIENTIFIC*  
 18          *REGISTRY.*—*Part I of title III of such Act (42 U.S.C. 274k*  
 19          *et seq.) is amended by adding at the end thereof the follow-*  
 20          *ing new section:*

21          “**SEC. 379B. BONE MARROW SCIENTIFIC REGISTRY.**

22               “(a) *ESTABLISHMENT.*—*The Secretary, acting through*  
 23          *the Donor Registry, shall establish and maintain a bone*  
 24          *marrow scientific registry of all recipients of biologic unre-*  
 25          *lated allogeneic marrow donors.*

1       “(b) *INFORMATION.*—*The bone marrow transplan-*  
2 *tation scientific registry established under subsection (a)*  
3 *shall include information with respect to patients who have*  
4 *received biologic unrelated allogeneic marrow transplant,*  
5 *transplant procedures, pretransplant and transplant costs,*  
6 *and other information the Secretary determines to be nec-*  
7 *essary to conduct an ongoing evaluation of the scientific*  
8 *and clinic status of unrelated allogeneic marrow transplan-*  
9 *tation.*”

10       “(c) *REPORT.*—*The Donor Registry shall submit to the*  
11 *Secretary on an annual basis a report using data collected*  
12 *and maintained by the bone marrow transplantation sci-*  
13 *entific registry established under subsection (a) concerning*  
14 *patient outcomes with respect to each transplant center and*  
15 *the pretransplant comparative costs involved at such trans-*  
16 *plant centers.*”

17       “(g) *AUTHORIZATION OF APPROPRIATIONS.*—*Part I of*  
18 *title III of such Act (42 U.S.C. 274k et seq.) as amended*  
19 *by subsection (f), is further amended by adding at the end*  
20 *thereof the following new section:*

21       “**SEC. 379C. AUTHORIZATION OF APPROPRIATIONS.**”

22       “*There are authorized to be appropriated to carry out*  
23 *section 379, \$13,500,000 for fiscal year 1997, \$12,150,000*  
24 *for fiscal year 1998, and such sums as may be necessary*  
25 *for fiscal year 1999.*”