

104TH CONGRESS
1ST SESSION

S. 1324

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.

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

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,*

3 **SECTION 1. SHORT TITLE.**

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

1 **TITLE I—SOLID-ORGAN**
2 **TRANSPLANT PROGRAM**

3 **SEC. 101. SHORT TITLE.**

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

6 **SEC. 102. ORGAN PROCUREMENT ORGANIZATIONS.**

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

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

15 “(A) the planning and conducting of programs
16 to provide information and education to the public
17 on the need for organ donations;

18 “(B) the training of individuals in requesting
19 such donations;

20 “(C) the provision of technical assistance to
21 organ procurement organizations and other entities
22 that can contribute to organ donation;

23 “(D) the performance of research and the per-
24 formance of demonstration programs by organ pro-

1 curement organizations and other entities that may
2 increase organ donation;

3 “(E) the voluntary consolidation of organ pro-
4 curement organizations and tissue banks; or

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

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

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

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

22 (1) in paragraph (1)—

23 (A) in the matter preceding subparagraph

24 (A)—

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

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

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

9 (C) in subparagraph (G)—

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

17 (ii) in clause (i)—

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

22 (II) by inserting before the
23 comma in subclause (II) the following:
24 “, including individuals who have re-
25 ceived a transplant of an organ (or

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

6 (III) by striking subclause (IV)
7 and inserting the following new
8 subclause:

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

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

21 (2) by striking paragraph (2);

22 (3) by redesignating paragraph (3) as para-
23 graph (2);

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

25 (A) in subparagraph (A)—

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

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

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

17 (B) by redesignating subparagraphs (B)
18 through (K) as subparagraphs (D) through
19 (M), respectively,

20 (C) by inserting after subparagraph (A)
21 the following new subparagraphs:

22 “(B) conduct and participate in systematic ef-
23 forts, including public education, to increase the
24 number of potential donors, including minority popu-

1 lations for which there is a greater degree of organ
2 shortage than that of the general population,

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

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

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

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

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

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

22 of individuals who have been medically referred to a
23 transplant center in the service area of the organiza-
24 tion in order to receive a transplant of the type of
25 organ with respect to which the list is maintained

1 and had been placed on an organ specific waiting
2 list;”;

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

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

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

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

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

19 “(ii) a subdivision of an organ procurement or-
20 ganization that operates as a distinct procurement
21 and distribution unit as a result of special geo-
22 graphic, rural, or minority population concerns but
23 that is not composed of any subunit of a metropoli-
24 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 (c) 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 (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
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 (e) 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 (c)(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. 274c) is amended—

1 (1) in section 375 (42 U.S.C. 274c), 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 (c), 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 proc-
21 ess 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 proc-
13 ess; 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 (c), to assist”.

18 (e) 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.”.

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