

104TH CONGRESS
2^D SESSION

S. 1324

AN ACT

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 1996”.

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 1996”.

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 populations for which
7 there is a greater degree of organ shortages relative
8 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 clause (i)—
- 11 (I) by striking “composed of” in
12 the matter preceding subclause (I)
13 and inserting “composed of a reason-
14 able balance of”;
- 15 (II) by inserting before the
16 comma in subclause (II) the following:
17 “, including individuals who have re-
18 ceived a transplant of an organ (or
19 transplant candidates), and individ-
20 uals who are part of the family of an
21 individual who has donated or re-
22 ceived an organ or who is a transplant
23 candidate”;

1 (III) by striking subclause (IV)
2 and inserting the following new sub-
3 clause:

4 “(IV) physicians or other health care
5 professionals with knowledge and skill in
6 the field of neurology, emergency medicine,
7 or trauma surgery”; and

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

16 (ii) in clause (ii), by inserting “, ad-
17 ministrative functions of the organ pro-
18 curement organization,” after “organs”;
19 and

20 (iii) in clause (iii), to read as follows:

21 “(iii) in the case of a hospital-based organ
22 procurement organization, has no authority
23 over any non-transplant-related activity of the
24 organization.”;

25 (2) by striking paragraph (2);

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

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

4 (A) in subparagraph (A)—

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

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

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

21 (B) by redesignating subparagraphs (B)
22 through (K) as subparagraphs (D) through
23 (M), respectively,

24 (C) by inserting after subparagraph (A)
25 the following new subparagraphs:

1 “(B) conduct and participate in systematic ef-
2 forts, including public education, to increase the
3 number of potential donors, including populations
4 for which there is a greater degree of organ shortage
5 than that of the general population,

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

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

14 “(i) a single list encompassing the entire
15 service area;

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

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

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

1 of individuals who have been medically referred to a
2 transplant center in the service area of the organiza-
3 tion in order to receive a transplant of the type of
4 organ with respect to which the list is maintained
5 and had been placed on an organ specific waiting
6 list;”;

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

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

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

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

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

23 “(ii) a subdivision of an organ procurement or-
24 ganization that operates as a distinct procurement
25 and distribution unit as a result of special geo-

1 graphic, rural, or population concerns but that is not
2 composed of any subunit of a metropolitan statistical
3 area.

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

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

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

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

1 **SEC. 103. ORGAN PROCUREMENT AND TRANSPLANTATION**
2 **NETWORK.**

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

6 “(a)(1) Congress finds that—

7 “(A) it is in the public interest to maintain and
8 improve a durable system for promoting and sup-
9 porting a central network to assist organ procure-
10 ment organizations in the nationwide distribution of
11 organs among transplant patients;

12 “(B) it is desirable to continue the partnership
13 between public and private enterprise, by continuing
14 to provide Federal Government oversight and assist-
15 ance for services performed by the Network; and

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

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

4 “(3) The Network shall be recognized as a private
5 entity that has an expertise in organ procurement and
6 transplantation with the primary purposes of encouraging
7 organ donation, maintaining a ‘wait list’, and operating
8 and monitoring an equitable and effective system for allo-
9 cating organs to transplant recipients, and shall report to
10 the Secretary instances of continuing noncompliance with
11 policies (or when promulgated, rules) and requirements of
12 the Network.

13 “(4) The Network may assess a fee (to be known as
14 the ‘patient registration fee’), to be collected by the con-
15 tractor for listing each potential transplant recipient on
16 its national organ matching system, in an amount which
17 is reasonable and customary and determined by the Net-
18 work and approved as such by the Secretary. The patient
19 registration fee shall be calculated so as to be sufficient
20 to cover the Network’s reasonable costs of operation in
21 accordance with this section. The Secretary shall have 60
22 days, beginning on the date on which the written applica-
23 tion justifying the proposed fee as reasonable is submitted
24 to the Secretary, to provide the Network with a written
25 determination and rationale for such determination that

1 the proposed increase is not reasonable and customary and
2 that the Secretary disapproves the recommendation of the
3 Network under this paragraph with respect to the change
4 in fee for listing each potential transplant recipient.

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

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

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

13 The patient registration fees shall not be increased more
14 than once during each year.

15 “(6) All fees collected by the Network contractor
16 under paragraph (4) shall be available to the Network
17 without fiscal year limitation. The contract with the Net-
18 work contractor shall provide that expenditures of such
19 funds (including patient registration fees collected by the
20 contractor and or contract funds) are subject to annual
21 audit under the provisions of the Office of Management
22 and Budget Circular No. A-133 entitled ‘Audits of Insti-
23 tutions of Higher Learning and Other Nonprofit Institu-
24 tions’. A report concerning the audit and recommenda-

1 tions regarding expenditures shall be submitted to the
2 Network, the contractor, and the Secretary.

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

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

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

13 Such data management fee shall be set annually by the
14 Network in an amount determined by the Network, in con-
15 sultation with the Secretary, and approved by the Sec-
16 retary. Such data management fee shall be calculated
17 based on the number of transplants performed or facili-
18 tated by each transplant hospital or center, or organ pro-
19 curement organization. The per transplant data manage-
20 ment fee shall be divided so that the patient specific trans-
21 plant center will pay 80 percent and the procuring organ
22 procurement organization will pay 20 percent of the per
23 transplant data management fee. Such fees shall be avail-
24 able to the Secretary and the contractor operating the Sci-
25 entific Registry without fiscal year limitation. The expend-

1 iture (including fees or contract funds) of such fees by
2 the contractor shall be subject to an annual independent
3 audit (performed by the Secretary or an authorized audi-
4 tor at the discretion of the Secretary) and reported along
5 with recommendations regarding such expenditures, to the
6 Network, the contractor and the Secretary.

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

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

13 (1) in paragraph (1)(B)—

14 (A) in clause (i)—

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

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

1 board members), and the Division of
2 Organ Transplantation of the Bureau of
3 Health Resources Development (the Health
4 Resources and Services Administration)
5 shall be represented at all meetings except
6 for those pertaining to the Network con-
7 tractor’s internal business;”;

8 (B) in clause (ii)—

9 (i) by inserting “including a patient
10 affairs committee and a minority affairs
11 committee” after “committees,”; and

12 (ii) by striking the period; and

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

15 “(iii) that shall include representation by a
16 member of the Division of Organ Transplan-
17 tation of the Bureau of Health Resources De-
18 velopment (the Health Resources and Services
19 Administration) as a representative at all meet-
20 ings (except for those portions of committee
21 meetings pertaining to the Network contractor’s
22 internal business) of all committees (including
23 the executive committee, finance committee,
24 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 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 organiza-
4 tions to membership on the Network Board of Directors
5 and all of its committees. Ensuring the reasonable mix of
6 all populations shall be a priority of the plan for imple-
7 mentation.”.

8 (e) REGULATIONS.—

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

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

20 (3) FAILURE TO ISSUE REGULATIONS BY DATE
21 CERTAIN.—If the Secretary fails to issue a final rule
22 under paragraph (1) prior to the expiration of the
23 period referred to in such paragraph, the Secretary
24 shall, not later than 30 days after the expiration of
25 such period, prepare and submit to the appropriate

1 committees of Congress a report describing the rea-
2 sons why the Secretary is not in compliance with
3 paragraph (1) and the plans that will be imple-
4 mented to provide for the issuance of the final rule
5 under such paragraph.

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

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

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

11 (2) in subsection (c)—

12 (A) by redesignating paragraph (1) and
13 (2) as paragraphs (2) and (3), respectively; and

14 (B) by inserting before paragraph (2) (as
15 so redesignated) the following new paragraph:

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

21 (3) by redesignating subsection (d) as sub-
22 section (e); and

23 (4) by adding at the end thereof the following
24 new subsection:

1 “(d) No contract in excess of \$25,000 may be made
2 under this part using funds withheld under subsection
3 (c)(1) unless an application for such contract has been
4 submitted to the Secretary, recommended by the Network
5 and approved by the Secretary. Such an application shall
6 be in such form and be submitted in such a manner as
7 the Secretary shall prescribe.”.

8 **SEC. 105. ADMINISTRATION.**

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

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

14 (2) in paragraph (3)—

15 (A) by striking “in the health care sys-
16 tem”; and

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

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

20 (4) by adding at the end thereof the following
21 new paragraph:

22 “(5) through contract, prepare a triennial organ
23 procurement organization specific data report (the
24 initial report to be completed not later than 18

1 months after the date of enactment of this para-
2 graph) that includes—

3 “(A) data concerning the effectiveness of
4 each organ procurement organization in acquir-
5 ing potentially available organs, particularly
6 among minority populations;

7 “(B) data concerning the variation of pro-
8 curement across hospitals within the organ pro-
9 curement organization region;

10 “(C) a plan to increase procurement, par-
11 ticularly among populations for which there is
12 a greater degree of organ shortages relative to
13 the general population; and

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

16 **SEC. 106. STUDY AND REPORT.**

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

19 **“SEC. 377. STUDY AND REPORT.**

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

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

1 “(A) the role of and the impact of the Fed-
2 eral Government in the oversight and support
3 of solid-organ transplantation, the Network
4 (which on the date of enactment of this section
5 carries out its functions by government con-
6 tract) and the solid organ transplantation sci-
7 entific registry; and

8 “(B) the access of all interested constitu-
9 encies and organizations to membership on the
10 Network board of directors and all Network
11 committees;

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

21 (b) REPORT.—Not later than 2 years after the date
22 of enactment of this section, the Institute of Medicine (or
23 other entity as the case may be) shall complete the study
24 required under subsection (a)(1) and prepare and submit
25 to the Committee on Labor and Human Resources of the

1 Senate, a report describing the findings made as a result
2 of the study.”.

3 **SEC. 107. GENERAL PROVISIONS.**

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

6 (1) in the section heading, by striking
7 “GRANTS AND”;

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

11 (3) in subsection (b)—

12 (A) in paragraph (1)—

13 (i) by striking “grant” and inserting
14 “contract”; and

15 (ii) by striking “and may not exceed
16 \$100,000”;

17 (B) by striking paragraph (2);

18 (C) by redesignating paragraph (3) as
19 paragraph (2); and

20 (D) in paragraph (2) (as so redesignig-
21 nated)—

22 (i) by striking “Grants or contracts”
23 and inserting “Contracts”; and

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

1 (4) in subsection (c)—

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

4 (B) in paragraph (1), by striking “grants
5 and”; and

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

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

12 **SEC. 108. AUTHORIZATION OF APPROPRIATION.**

13 Part H of title III of the Public Health Service Act
14 (42 U.S.C. 273 et seq.) is amended by adding at the end
15 thereof the following new section:

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

17 “There are authorized to be appropriated to carry out
18 sections 371, 372, 375 and 377, \$1,950,000 for fiscal year
19 1997, and \$1,100,000 for fiscal year 1998, and to carry
20 out section 371, \$250,000 for each of the fiscal years 1999
21 through 2001.”.

22 **SEC. 109. EFFECTIVE DATES.**

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

1 **TITLE II—BONE MARROW**
2 **DONOR PROGRAM**

3 **SEC. 201. SHORT TITLE.**

4 This title may be cited as the “Bone Marrow Trans-
5 plantation Program Reauthorization Act of 1996”.

6 **SEC. 202. REAUTHORIZATION.**

7 (a) ESTABLISHMENT OF DONOR REGISTRY.—Section
8 379(a) of the Public Health Service Act (42 U.S.C.
9 274k(a)) is amended—

10 (1) by striking “‘Registry’” and inserting
11 “‘Donor Registry’”;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(A) the priority to increase potential mar-
10 row donors for which there is a greater degree
11 of marrow donor shortage than that of the gen-
12 eral population; and

13 “(B) the compilation and distribution of
14 informational materials to educate and update
15 potential donors;”;

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

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

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

22 “(7) not later than 1 year after the date on
23 which the ‘Bone Marrow Program Inspection’ (here-
24 after referred to in this part as the ‘Inspection’) that
25 is being conducted by the Office of the Inspector

1 General on the date of enactment of this paragraph
2 is completed, in consultation with the Secretary, and
3 based on the findings and recommendations of the
4 Inspection, the marrow donor program shall develop,
5 evaluate, and implement a plan to streamline and
6 make more efficient the relationship between the
7 Donor Registry and donor centers;”.

8 (c) INFORMATION AND EDUCATION PROGRAM.—Sec-
9 tion 379 of such Act (42 U.S.C. 274k) is amended by
10 striking subsection (j), and inserting the following new
11 subsection:

12 “(j) INFORMATION AND EDUCATION PROGRAM.—

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

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

23 “(B) plan and conduct programs to pro-
24 vide information and education to the public on
25 the availability of unrelated donor marrow

1 transplants and the need for donations of bone
2 marrow;

3 “(C) train individuals in requesting bone
4 marrow donations; and

5 “(D) recruit, test and enroll marrow do-
6 nors with the priority being groups for which
7 there is a greater degree of marrow donor
8 shortage than that of the general population.

9 “(2) PRIORITIES.—In awarding contracts under
10 paragraph (1), the Secretary shall give priority to
11 carrying out the purposes described in such para-
12 graph with respect to population groups with such
13 shortages.”.

14 (d) PATIENT ADVOCACY AND CASE MANAGEMENT.—

15 (1) IN GENERAL.—Section 379 of such Act (42
16 U.S.C. 274k), as amended by subsection (c), is
17 amended by adding at the end thereof the following
18 new subsection:

19 “(k) PATIENT ADVOCACY AND CASE MANAGE-
20 MENT.—

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

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

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

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

8 “(ii) the physicians involved; and

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

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

16 “(C) provide individual case management
17 services as appropriate to directly assist individ-
18 uals and physicians referred to in subparagraph
19 (A), including—

20 “(i) individualized case assessment
21 and tracking of preliminary search through
22 activation (including when the search proc-
23 ess is interrupted or discontinued);

1 “(ii) informing individuals and physi-
2 cians on regular intervals of progress made
3 in searching for appropriate donors; and

4 “(iii) identifying and resolving individ-
5 ual search problems or concerns;

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

13 “(E) survey patients to evaluate how well
14 such patients are being served and make rec-
15 ommendations for expediting the search proc-
16 ess; and

17 “(F) provide individual case management
18 services to individual marrow donors.

19 “(3) EVALUATION.—

20 “(A) IN GENERAL.—The Secretary shall
21 evaluate the system established under para-
22 graph (1) and make recommendations concern-
23 ing the success or failure of such system in im-
24 proving patient satisfaction, and any impact the

1 system has had on assisting individuals in pro-
2 ceeding to transplant.

3 “(B) REPORT.—Not later than April 1,
4 1996, the Secretary shall prepare and make
5 available a report concerning the evaluation
6 conducted under subparagraph (A), including
7 the recommendations developed under such sub-
8 paragraph.”.

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

22 (e) STUDY AND REPORTS.—Section 379A of such Act
23 (42 U.S.C. 274l) is amended to read as follows:

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

2 “(a) EVALUATION BY THE INSTITUTE OF MEDI-
3 CINE.—

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

7 “(A) the role of a national bone marrow
8 transplant program supported by the Federal
9 Government in facilitating the maximum num-
10 ber of unrelated marrow donor transplants; and

11 “(B) other possible clinical or scientific
12 uses of the potential donor pool or accompany-
13 ing information maintained by the Donor Reg-
14 istry or the unrelated marrow donor scientific
15 registry.

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

25 “(3) REPORT.—Not later than 2 years after the
26 date of enactment of this section, the Institute of

1 Medicine (or other entity as the case may be) shall
2 complete the study required under paragraph (1)
3 and prepare and submit to the Committee on Labor
4 and Human Resources of the Senate, a report de-
5 scribing the findings made as a result of the study.

6 “(b) BONE MARROW CONSOLIDATION.—

7 “(1) IN GENERAL.—The Secretary shall con-
8 duct—

9 “(A) an evaluation of the feasibility of in-
10 tegrating or consolidating all federally funded
11 bone marrow transplantation scientific reg-
12 istries, regardless of the type of marrow recon-
13 stitution utilized; and

14 “(B) an evaluation of all federally funded
15 bone marrow transplantation research to be
16 conducted under the direction and administra-
17 tion of the peer review system of the National
18 Institutes of Health.

19 “(2) REPORT.—Not later than 1 year after the
20 date of enactment of this section, the Secretary shall
21 prepare and submit to the Committee on Labor and
22 Human Resources of the Senate a report concerning
23 the evaluations conducted under paragraph (1).

24 “(3) DEFINITION.—As used in paragraph (1),
25 the term ‘marrow reconstitution’ shall encompass all

1 sources of hematopoietic cells including marrow
2 (autologous, related or unrelated allogeneic,
3 syngeneic), autologous marrow, allogeneic marrow
4 (biologically related or unrelated), umbilical cord
5 blood cells, peripheral blood progenitor cells, or other
6 approaches that may be utilized.”.

7 (f) BONE MARROW TRANSPLANTATION SCIENTIFIC
8 REGISTRY.—Part I of title III of such Act (42 U.S.C.
9 274k et seq.) is amended by adding at the end thereof
10 the following new section:

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

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

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

1 “(c) REPORT.—The Donor Registry shall submit to
2 the Secretary on an annual basis a report using data col-
3 lected and maintained by the bone marrow transplantation
4 scientific registry established under subsection (a) con-
5 cerning patient outcomes with respect to each transplant
6 center and the pretransplant comparative costs involved
7 at such transplant centers.”.

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

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

13 “There are authorized to be appropriated to carry out
14 section 379, \$13,500,000 for fiscal year 1997,
15 \$12,150,000 for fiscal year 1998, and such sums as may
16 be necessary for fiscal year 1999.”.

Passed the Senate September 9, 1996.

Attest:

Secretary.

104TH CONGRESS
2^D SESSION

S. 1324

AN ACT

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.