

Calendar No. 378

103^D CONGRESS
2^D SESSION

S. 1597

[Report No. 103-233]

A BILL

To amend the Public Health Service Act to revise and extend certain organ procurement and transplantation programs, and for other purposes.

MARCH 7 (legislative day, FEBRUARY 22), 1994

Reported with an amendment

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To amend the Public Health Service Act to revise and extend certain organ procurement and transplantation programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 27 (legislative day, OCTOBER 13), 1993

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

MARCH 7 (legislative day, FEBRUARY 22), 1994

Reported by Mr. KENNEDY, with an amendment

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

A BILL

To amend the Public Health Service Act to revise and extend certain organ procurement and transplantation programs, 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 Transplant Pro-
5 gram Reauthorization Act of 1993”.

1 **SEC. 2. ORGAN PROCUREMENT ORGANIZATIONS.**

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

5 “(a)(1) The Secretary may make grants for the con-
6 solidation and expansion of qualified organ procurement
7 organizations described in subsection (b).

8 “(2) The Secretary may make grants to, and enter
9 into cooperative agreements and contracts with, qualified
10 organ procurement organizations described in subsection
11 (b) and other public or nonprofit private entities for the
12 purpose of increasing organ donation through—

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

16 “(B) the training of individuals in requesting
17 such donations; or

18 “(C) the provision of technical assistance to
19 organ procurement organizations and other entities
20 in the health care system.

21 “(3)(A) In making awards of grants, cooperative
22 agreements and contracts under subparagraphs (A) and
23 (B) of paragraph (2), the Secretary shall give priority to
24 carrying out the purpose described in such paragraph with
25 respect to minority or other populations for which there

1 is a greater degree of organ shortages relative to the gen-
2 eral population.

3 “(B) In making awards of grants, cooperative agree-
4 ments and contracts under paragraph (2)(C), the Sec-
5 retary shall give priority to carrying out the purpose de-
6 scribed in such paragraph with respect to organ procure-
7 ment organizations and hospitals with lower rates of pro-
8 curement relative to other such organizations or hos-
9 pitals.”.

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

13 (1) in paragraph (1)—

14 (A) in the matter preceding subparagraph
15 (A), by striking “for which grants may be made
16 under subsection (a)” and inserting “described
17 in this section”;

18 (B) by realigning the margin of subpara-
19 graph (E) so as to align with the margin of
20 subparagraph (D); and

21 (C) in subparagraph (G)—

22 (i) in the matter preceding clause (i),
23 by striking “directors or an advisory
24 board” and inserting “directors (or an ad-
25 visory board, in the case of a hospital-

1 based organ procurement organization es-
2 tablished prior to September 1, 1993)”;
3 and

4 (ii) in clause (i)—

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

9 (II) by inserting before the
10 comma in subclause (II) the following:
11 “, including individuals who have re-
12 ceived a transplant of an organ (or
13 transplant candidates), and individ-
14 uals who are part of the family of an
15 individual who has donated an
16 organ”;

17 (2) by striking paragraph (2);

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

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

21 (A) by striking subparagraph (A) and in-
22 serting the following new subparagraph:

23 “(A) with respect to each hospital or other en-
24 tity in its service area that has facilities for organ

1 donations, and except as provided in paragraph
2 (3)—

3 “(i) have in effect an agreement with the
4 entity under which the entity, for the purposes
5 of allocation, identifies potential organ donors
6 and notifies the organ procurement organiza-
7 tion, and

8 “(ii) if such hospital or entity is dissatis-
9 fied with the service obtained from its des-
10 ignated organ procurement organization such
11 hospital or entity may seek mediation under a
12 process established by the Secretary within 60
13 days after the date of enactment of this sub-
14 paragraph,”;

15 (B) by redesignating subparagraphs (B)
16 through (K) as subparagraphs (C) through (L),
17 respectively;

18 (C) by inserting after subparagraph (A)
19 the following new subparagraph:

20 “(B) conduct and participate in systematic ef-
21 forts, including public education, to increase the
22 number of potential donors,”;

23 (D) by inserting before the comma in sub-
24 paragraph (F) (as so redesignated) the follow-
25 ing: “, which system shall, at a minimum, allo-

1 cate each type of organ either on the basis of
2 a single service area list, or an approved alter-
3 nate local unit list (as defined in paragraph
4 (4)), of individuals who have been medically re-
5 ferred to a transplant center in the service area
6 of the organization in order to receive a trans-
7 plant of the type of organ with respect to which
8 the list is maintained”;

9 (E) by striking subparagraph (I) (as so re-
10 designated) and inserting the following new
11 subparagraph:

12 “(I) be a member of and abide by the rules and
13 requirements of the Organ Procurement and Trans-
14 plantation Network established under section 372,”;

15 (F) by striking subparagraph (K) (as so
16 redesignated) and inserting the following new
17 subparagraph:

18 “(K) evaluate annually, and report to the
19 Organ Procurement and Transplantation Network
20 established under section 372, on the effectiveness of
21 the organization in acquiring potentially available or-
22 gans, particularly among minority populations, and
23 the variation of procurement across hospitals within
24 the organ procurement organization region, and
25 identify a plan to increase procurement, particularly

1 among minority populations and other populations
2 for which there is a greater degree of organ short-
3 ages relative to the general population, and at hos-
4 pitals with low rates of procurement,”; and

5 (G) by adding at the end thereof the fol-
6 lowing flush sentence:

7 “Subparagraph (A) shall not be construed as precluding
8 an organ procurement organization from requesting that
9 the Secretary permit changes in their service area bound-
10 aries.”; and

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

13 “(3)(A) The Secretary may waive the requirement
14 that an organ procurement organization have an agree-
15 ment of the type described in paragraph (2)(A) in effect
16 if—

17 “(i)(I) the hospital or other entity within the
18 service area of the organ procurement organization
19 is or seeks to be a party to such an agreement with
20 another organ procurement organization; and

21 “(ii) the hospital and organ procurement orga-
22 nization can demonstrate to the satisfaction of the
23 Secretary that their affiliation is based on an agree-
24 ment or understanding between the organ procure-
25 ment organization for the service area in which the

1 hospital is located, and the organ procurement orga-
2 nization with which the hospital desires to affiliate,
3 and such hospital;

4 “(ii) the hospital or other entity within the
5 service area of the organ procurement organization
6 is or seeks to be a party to such an agreement with
7 another organ procurement organization and can
8 document to the satisfaction of the Secretary, with
9 input from the organ procurement organization for
10 the area in which the hospital is located, that—

11 “(I) such hospital or entity has received in-
12 adequate service from the organ procurement
13 organization for the service area in which the
14 hospital is located; and

15 “(II) another organ procurement organiza-
16 tion is willing and able to provide such hospital
17 or entity adequate service; or

18 “(iii) in such other circumstances as described
19 in regulations promulgated by the Secretary.

20 “(B) The relationship of a hospital or other entity
21 within the service area of the organ procurement organiza-
22 tion with other organ procurement organizations outside
23 the service area that was in effect as of June 29, 1993,
24 may continue in effect, pending a determination by the
25 Secretary under the waiver process described in subpara-

1 graph (A). Not later than 3 months after the date of en-
2 actment of this paragraph, the hospital or other entity
3 shall notify the Secretary in writing of its intent to proceed
4 with such an existing relationship.

5 “(C)(i) The Office of Technology Assessment shall
6 conduct a study for the purpose of defining—

7 “(I) the appropriate standards by which to
8 judge the quality of performance of organ procure-
9 ment organizations;

10 “(II) the proper criteria for a determination of
11 inadequate service from an organ procurement orga-
12 nization; and

13 “(III) the process for allowing a hospital to
14 work with an organ procurement organization out-
15 side its service area.

16 “(ii) Not later than 1 year after the date of enact-
17 ment of this paragraph, the Office of Technology Assess-
18 ment shall complete the study required under clause (i)
19 and prepare and submit to the Committee on Labor and
20 Human Resources of the Senate, the Committee on En-
21 ergy and Commerce of the House of Representatives, and
22 the Secretary, a report describing the findings made as
23 a result of the study.

24 “(4)(A) As used in paragraph (2)(F), the term ‘alter-
25 native local unit’ means—

1 “(i) a unit composed of two or more contiguous
2 organ procurement organizations; or

3 ~~“(ii) a subdivision of an organ procurement or-~~
4 ~~ganization that operates as a distinct procurement~~
5 ~~and distribution unit as a result of special geo-~~
6 ~~graphic or minority population concerns but that is~~
7 ~~not composed of any subunit of a metropolitan sta-~~
8 ~~tistical area.~~

9 ~~“(B) The Organ Procurement and Transplantation~~
10 ~~Network shall make recommendations to the Secretary~~
11 ~~concerning the approval or denial of alternative local unit.~~
12 ~~The Network shall assess whether the alternative local~~
13 ~~units will better promote organ donation and the equitable~~
14 ~~allocation of organs.~~

15 ~~“(C) The Secretary shall approve or deny any alter-~~
16 ~~native local unit principle or designation recommended by~~
17 ~~the Network. If the Secretary does not provide otherwise~~
18 ~~prior to the expiration of the 90-day period beginning on~~
19 ~~the date on which the application is submitted, the rec-~~
20 ~~ommendations of the Network under subparagraph (B)~~
21 ~~with respect to the application of the alternative local unit~~
22 ~~shall go into effect.”.~~

1 **SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION**
2 **NETWORK.**

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

5 (1) in paragraph (1)(B)—

6 (A) in clause (i)—

7 (i) by striking “(including organiza-
8 tions that have received grants under sec-
9 tion 371)”;

10 (ii) by striking “and” at the end
11 thereof and inserting “including both indi-
12 viduals who have received a transplant of
13 an organ (or transplant candidates), and
14 individuals who are part of the family of
15 individuals who have donated an organ, the
16 number of whom shall make up not less
17 than 33 percent of the total number of
18 board members”;

19 (B) in clause (ii), by inserting “including a
20 patient affairs committee” after “committees.”;

21 (2) in paragraph (2)—

22 (A) by striking clause (A)(i) and inserting
23 the following new clause:

24 “(i) with respect to each type of trans-
25 plant, a national list of individuals who have
26 been medically referred to receive a transplant

1 of the type of organs with respect to which the
2 list is maintained (which list shall include the
3 names of all individuals included on lists in ef-
4 fect under section 371(b)(2)(F), and”;

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

8 (C) in subparagraph (D), to read as fol-
9 lows:

10 “(D) develop and report to the Secretary, not
11 later than September 30, 1994, and implement not
12 later than September 30, 1995, a system of allocat-
13 ing organs in order to ensure that patients in one
14 region have an equivalent probability of receiving an
15 organ as do patients with similar characteristics in
16 another region,”;

17 (D) by redesignating subparagraphs (E)
18 through (L), as subparagraphs (F) through
19 (M), respectively;

20 (E) by inserting after subparagraph (D),
21 the following new subparagraph:

22 “(E) assist organ procurement organizations in
23 the equitable distribution of organs among trans-
24 plant patients,”;

1 ~~(F)~~ in subparagraph ~~(K)~~ (as so redesignated), by striking “and” at the end thereof;

2
3 ~~(G)~~ in subparagraph ~~(L)~~ (as so redesignated), by striking the period and inserting “,
4 including making recommendations to organ
5 procurements organizations and the Secretary
6 based on the annual reports required under sec-
7 tion 371(b)(2)(K),”;

8
9 ~~(H)~~ in subparagraph ~~(M)~~ (as so redesignated), by striking the period and inserting a
10 comma; and

11
12 ~~(I)~~ by adding at the end thereof the follow-
13 ing new subparagraphs:

14 “~~(N)~~ submit to the Secretary for review and ap-
15 proval any change in the amount of fees imposed by
16 the Network for the registration of individuals on
17 the lists maintained under subparagraph ~~(A)~~(i); such
18 change to be considered as approved if the Secretary
19 does not provide otherwise prior to the expiration of
20 the 90-day period beginning on the date on which
21 the change is submitted to the Secretary,

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

1 ~~“(P) submit to the Secretary, on an annual~~
 2 ~~basis, a report on the clinical and scientific status of~~
 3 ~~the organ transplantations, and~~

4 ~~“(Q) meet such other criteria regarding compli-~~
 5 ~~ance with this part as the Secretary may establish.”;~~
 6 ~~and~~

7 ~~(3) by adding at the end thereof the following~~
 8 ~~new paragraph:~~

9 ~~“(3) In carrying out paragraph (2)(D), the Organ~~
 10 ~~Procurement and Transplantation Network shall consult~~
 11 ~~with experts in the area of organ allocation and organ do-~~
 12 ~~nations and consider their recommendations regarding the~~
 13 ~~establishment of regions in the country for the purpose~~
 14 ~~of allocating organs.”.~~

15 ~~**SEC. 4. STUDY BY GENERAL ACCOUNTING OFFICE.**~~

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

18 ~~**“SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.**~~

19 ~~“(a) IN GENERAL.—The Comptroller General of the~~
 20 ~~United States shall conduct a study for the purpose of~~
 21 ~~determining and making recommendations concerning—~~

22 ~~“(1) the composition of the boards of directors~~
 23 ~~of organ procurement organizations and of the~~
 24 ~~Organ Procurement and Transplantation Network~~
 25 ~~on the date of enactment of this section, and the ef-~~

1 fect of the Organ Transplant Program Reauthoriza-
2 tion Act of 1993 on the composition and functioning
3 of such boards;

4 ~~“(2)(A) the number and percentage of cadaveric~~
5 organ transplants for foreign nationals categorized
6 by organ procurement organization and by trans-
7 plant center;

8 ~~“(B) the number and percent of the organiza-~~
9 tions referred to in subparagraph (A) above the
10 organ procurement transplant network guideline of
11 10 percent; and

12 ~~“(C) any information on the current rate of~~
13 organ donation by individuals other than United
14 States citizens or legal residents;

15 ~~“(3) the equitable allocation of organs nation-~~
16 wide, including an analysis of the relative probability
17 of receiving an organ for patients with similar char-
18 acteristics for each category of transplanted organ
19 by organ procurement organization and the effect of
20 the Organ Transplant Program Reauthorization Act
21 of 1993 on improving the equitable allocation of or-
22 gans nationwide.

23 ~~“(b) REPORT.—Not later than 2 years after the date~~
24 of enactment of the Organ Transplant Program Reauthor-
25 ization Act of 1993, the Comptroller General of the United

1 States shall complete the study required under subsection
2 (a) and prepare and submit to the Committee on Energy
3 and Commerce of the House of Representatives, and to
4 the Committee on Labor and Human Resources of the
5 Senate, a report describing the findings made as a result
6 of the study.”.

7 **SEC. 5. GENERAL PROVISIONS.**

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

10 (1) by striking paragraph (2);

11 (2) by redesignating paragraph (3) as para-
12 graph (2); and

13 (3) in paragraph (2) (as so redesignated), by
14 striking “371(a)(3)” and inserting “371(a)(2)”.

15 (b) **REPEAL.**—Section 376 of the Public Health Serv-
16 ice Act (42 U.S.C. 274d) is repealed.

17 (c) **TRANSFER.**—Section 378 of the Public Health
18 Service Act (42 U.S.C. 274g) is amended—

19 (1) by transferring such section to part H of
20 title III; and

21 (2) by inserting such section after section 377.

22 (d) **AUTHORIZATION OF APPROPRIATIONS.**—Section
23 378 of the Public Health Service Act (42 U.S.C. 274g)
24 is amended by striking “1991” and all that follows
25 through the period and inserting “1994, and such sums

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

3 **SEC. 6. EFFECTIVE DATES.**

4 (a) ~~IN GENERAL.~~—Except as provided in subsection
5 (b), the amendments made by this Act shall become effec-
6 tive on the date of enactment of this Act.

7 (b) ~~EXCEPTION.~~—The amendments made by sections
8 2(b)(4)(A) and 2(b)(4)(D) shall become effective 6 months
9 after the date of enactment of this Act. Prior to such date,
10 sections 371(b)(3)(A) and 371(b)(3)(E) of the Public
11 Health Service Act, as in effect on the day before the date
12 of the enactment of this Act, shall remain in effect.

13 **SECTION 1. SHORT TITLE.**

14 *This Act may be cited as the “Organ Transplant*
15 *Program Reauthorization Act of 1993”.*

16 **SEC. 2. ORGAN PROCUREMENT ORGANIZATIONS.**

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

20 “(a)(1) *The Secretary may make grants for the consoli-*
21 *ation and expansion of qualified organ procurement orga-*
22 *nizations described in subsection (b).*

23 “(2) *The Secretary may make grants to, and enter into*
24 *cooperative agreements and contracts with, qualified organ*
25 *procurement organizations described in subsection (b) and*

1 *other public or nonprofit private entities for the purpose*
2 *of increasing organ donation through—*

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

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

8 “(C) *the provision of technical assistance to*
9 *organ procurement organizations and other entities*
10 *in the health care system.*

11 “(3)(A) *In making awards of grants, cooperative*
12 *agreements and contracts under subparagraphs (A) and (B)*
13 *of paragraph (2), the Secretary shall give priority to carry-*
14 *ing out the purpose described in such paragraph with re-*
15 *spect to minority or other populations for which there is*
16 *a greater degree of organ shortages relative to the general*
17 *population.*

18 “(B) *In making awards of grants, cooperative agree-*
19 *ments and contracts under paragraph (2)(C), the Secretary*
20 *shall give priority to carrying out the purpose described in*
21 *such paragraph with respect to organ procurement organi-*
22 *zations and hospitals with lower rates of procurement rel-*
23 *ative to other such organizations or hospitals.”.*

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

4 (1) *in paragraph (1)—*

5 (A) *in the matter preceding subparagraph*
6 *(A), by striking “for which grants may be made*
7 *under subsection (a)” and inserting “described*
8 *in this section”;*

9 (B) *by realigning the margin of subpara-*
10 *graph (E) so as to align with the margin of sub-*
11 *paragraph (D); and*

12 (C) *in subparagraph (G)—*

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

19 (ii) *in clause (i)—*

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

24 (II) *by inserting before the comma*
25 *in subclause (II) the following: “, in-*

1 *cluding individuals who have received*
2 *a transplant of an organ (or trans-*
3 *plant candidates), and individuals who*
4 *are part of the family of an individual*
5 *who has donated an organ”;*

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

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

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

10 *(A) by redesignating subparagraphs (B)*
11 *through (K) as subparagraphs (C) through (L),*
12 *respectively,*

13 *(B) by inserting after subparagraph (A) the*
14 *following new subparagraph:*

15 *“(B) conduct and participate in systematic ef-*
16 *forts, including public education, to increase the num-*
17 *ber of potential donors,”;*

18 *(C) by inserting before the comma in sub-*
19 *paragraph (F) (as so redesignated) the following:*

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

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

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

1 “(iii) a list that encompasses an approved
2 alternative local unit (as defined in paragraph
3 (4)),

4 of individuals who have been medically referred to a
5 transplant center in the service area of the organiza-
6 tion in order to receive a transplant of the type of
7 organ with respect to which the list is maintained;”;

8 (D) by striking subparagraph (I) (as so re-
9 designated) and inserting the following new sub-
10 paragraph:

11 “(I) be a member of and abide by the rules and
12 requirements of the Organ Procurement and Trans-
13 plantation Network established under section 372,”;
14 and

15 (E) by striking subparagraph (K) (as so re-
16 designated) and inserting the following new sub-
17 paragraph:

18 “(K) evaluate annually, and report to the Organ
19 Procurement and Transplantation Network estab-
20 lished under section 372, on the effectiveness of the or-
21 ganization in acquiring potentially available organs,
22 particularly among minority populations, and the
23 variation of procurement across hospitals within the
24 organ procurement organization region, and identify
25 a plan to increase procurement, particularly among

1 *minority populations and other populations for which*
2 *there is a greater degree of organ shortages relative to*
3 *the general population, and at hospitals with low*
4 *rates of procurement, and”;* and

5 *(5) by adding at the end thereof the following*
6 *new paragraphs:*

7 *“(3)(A) The Office of Technology Assessment shall con-*
8 *duct a study for the purpose of defining—*

9 *“(i) the appropriate standards by which to judge*
10 *the quality of performance of organ procurement or-*
11 *ganizations; and*

12 *“(ii) the proper criteria for a determination of*
13 *inadequate service from an organ procurement orga-*
14 *nization.*

15 *“(B) Not later than 2 years after the date of enactment*
16 *of this paragraph, the Office of Technology Assessment shall*
17 *complete the study required under subparagraph (A) and*
18 *prepare and submit to the Committee on Labor and Human*
19 *Resources of the Senate, the Committee on Energy and*
20 *Commerce of the House of Representatives, and the Sec-*
21 *retary, a report describing the findings made as a result*
22 *of the study.*

23 *“(C) For purposes of this paragraph the term ‘organ’*
24 *means a human kidney, liver, heart, lung, pancreas, and*

1 *any other human organ or tissue specified by the Secretary*
2 *for purposes of this paragraph.*

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

5 “(i) *a unit composed of two or more contiguous*
6 *organ procurement organizations; or*

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

13 “(B) *The Organ Procurement and Transplantation*
14 *Network shall make recommendations to the Secretary con-*
15 *cerning the approval or denial of alternative local units.*
16 *The Network shall assess whether the alternative local units*
17 *will better promote organ donation and the equitable alloca-*
18 *tion of organs.*

19 “(C) *The Secretary shall approve or deny any alter-*
20 *native local unit principle or designation recommended by*
21 *the Network. If the Secretary does not provide otherwise*
22 *prior to the expiration of the 90-day period beginning on*
23 *the date on which the application is submitted, the rec-*
24 *ommendations of the Network under subparagraph (B) with*

1 *respect to the application of the alternative local unit shall*
 2 *go into effect.”.*

3 (c) *EFFECTIVE DATE.*—*The amendments made by sub-*
 4 *section (b)(5) shall apply to organ procurement organiza-*
 5 *tions beginning January 1, 1995.*

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

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

10 (1) *in paragraph (1)(B)—*

11 (A) *in clause (i)—*

12 (i) *by striking “(including organiza-*
 13 *tions that have received grants under sec-*
 14 *tion 371)”;* and

15 (ii) *by striking “; and” at the end*
 16 *thereof and inserting “(including both indi-*
 17 *viduals who have received a transplant of*
 18 *an organ (or transplant candidates), and*
 19 *individuals who are part of the family of*
 20 *individuals who have donated an organ, the*
 21 *number of whom shall make up not less*
 22 *than 40 percent of the total number of*
 23 *board members); and”;* and

1 (B) in clause (ii), by inserting “including
2 a patient affairs committee” after “committees,”;
3 and

4 (2) in paragraph (2)—

5 (A) in subparagraph (A), by striking clause
6 (i) and inserting the following new clause:

7 “(i) with respect to each type of transplant,
8 a national list of individuals who have been
9 medically referred to receive a transplant of the
10 type of organs with respect to which the list is
11 maintained (which list shall include the names
12 of all individuals included on lists in effect
13 under section 371(b)(2)(F), and”;

14 (B) in subparagraph (B), by inserting “,
15 including requirements under section 371(b),”
16 after “membership criteria”;

17 (C) by redesignating subparagraphs (E)
18 through (L), as subparagraphs (F) through (M),
19 respectively;

20 (D) by inserting after subparagraph (D),
21 the following new subparagraph:

22 “(E) assist organ procurement organizations in
23 the equitable distribution of organs among transplant
24 patients,”;

1 (E) in subparagraph (K) (as so redesignated), by striking “and” at the end thereof;

2
3 (F) in subparagraph (L) (as so redesignated), by striking the period and inserting “, including making recommendations to organ
4 procurements organizations and the Secretary
5 based on the annual reports required under section 371(b)(2)(K),”;

6
7 (G) in subparagraph (M) (as so redesignated), by striking the period and inserting a
8 comma; and

9 (H) by adding at the end thereof the following new subparagraphs:

10 “(N) submit to the Secretary for review and approval any change in the amount of fees imposed by
11 the Network for the registration of individuals on the
12 lists maintained under subparagraph (A)(i), such
13 change to be considered as approved if the Secretary
14 does not provide otherwise prior to the expiration of
15 the 90-day period beginning on the date on which the
16 change is submitted to the Secretary,

17 “(O) make available to the Secretary such information, books, and records regarding the Network as
18 the Secretary may require,

1 “(P) submit to the Secretary, on an annual
2 basis, a report on the clinical and scientific status of
3 the organ transplantations, and

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

6 **SEC. 4. STUDY BY GENERAL ACCOUNTING OFFICE.**

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

9 **“SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.**

10 “(a) *STUDY.*—

11 “(1) *IN GENERAL.*—The Comptroller General of
12 the United States shall conduct a study for the pur-
13 pose of determining and making recommendations
14 concerning—

15 “(A) the composition of the boards of direc-
16 tors of organ procurement organizations and of
17 the Organ Procurement and Transplantation
18 Network on the date of enactment of this section,
19 and the effect of the Organ Transplant Program
20 Reauthorization Act of 1993 on the composition
21 and functioning of such boards;

22 “(B)(i) the number and percentage of
23 cadaveric organ transplants for foreign nationals
24 and nonresident aliens categorized by organ pro-
25 curement organization and by transplant center

1 *and information on any reciprocal agreements*
2 *between organ procurement organizations and*
3 *foreign countries or territories;*

4 “(ii) *the number and percent of the organi-*
5 *zations referred to in clause (i) above the organ*
6 *procurement transplant network guideline of 10*
7 *percent; and*

8 “(III) *any information on the current rate*
9 *of organ donation by individuals other than*
10 *United States citizens or legal residents;*

11 “(C) *organ donation rates and the impact*
12 *of various organ allocation systems on organ*
13 *procurement rates; and*

14 “(D) *the equitable allocation of organs na-*
15 *tionwide, including an analysis of the relative*
16 *probability of receiving an organ for patients*
17 *with similar characteristics for each category of*
18 *transplanted organ by organ procurement orga-*
19 *nization and recommendations for developing a*
20 *regional allocation system in order to ensure*
21 *that—*

22 “(i) *patients in one region have an*
23 *equivalent probability of receiving an organ*
24 *as do patients with similar characteristics*
25 *in another region; and*

1 “(ii) patients within a region have an
2 equivalent probability of receiving an organ
3 as do other patients with similar character-
4 istics in that region.

5 “(2) *EQUITABLE ALLOCATION*.—In carrying out
6 paragraph (1) with respect to subparagraph (D), the
7 Comptroller General shall—

8 “(A) recommend regions for allocating or-
9 gans to encompass as large a geographic area as
10 is practical, taking into account medical appro-
11 priateness, and the geographic proximity of pa-
12 tients with comparable priority for receiving an
13 organ;

14 “(B) take into account the impact on organ
15 donation and procurement rates; and

16 “(C) consult with experts in the area of organ al-
17 location and organ donations and consider their rec-
18 ommendations regarding the establishment of regions
19 in the country for the purpose of allocating organs.

20 “(b) *REPORT*.—Not later than 2 years after the date
21 of enactment of the Organ Transplant Program Reauthor-
22 ization Act of 1993, the Comptroller General of the United
23 States shall complete the study required under subsection
24 (a) and prepare and submit to the Committee on Energy
25 and Commerce of the House of Representatives, and to the

1 *Committee on Labor and Human Resources of the Senate,*
2 *a report describing the findings made as a result of the*
3 *study.”.*

4 **SEC. 5. GENERAL PROVISIONS.**

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

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

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

10 (3) *in paragraph (2) (as so redesignated), by*
11 *striking “371(a)(3)” and inserting “371(a)(2)”.*

12 (b) *REPEAL.*—*Section 376 of the Public Health Service*
13 *Act (42 U.S.C. 274d) is repealed.*

14 (c) *TRANSFER.*—*Section 378 of the Public Health*
15 *Service Act (42 U.S.C. 274g) is amended—*

16 (1) *by transferring such section to part H of title*
17 *III; and*

18 (2) *by inserting such section after section 377.*

19 (d) *AUTHORIZATION OF APPROPRIATIONS.*—*Section*
20 *378 of the Public Health Service Act (42 U.S.C. 274g) is*
21 *amended by striking “1991” and all that follows through*
22 *the period and inserting “1994, and such sums as may be*
23 *necessary for each of the fiscal years 1995 and 1996.”.*

1 **SEC. 6. EFFECTIVE DATES.**

2 (a) *IN GENERAL.*—*Except as provided in subsection*
3 *(b), the amendments made by this Act shall become effective*
4 *on the date of enactment of this Act.*

5 (b) *EXCEPTION.*—*The amendments made by section*
6 *2(b)(4)(C) shall become effective 9 months after the date of*
7 *enactment of this Act. Prior to such date, section*
8 *371(b)(3)(E) of the Public Health Service Act, as in effect*
9 *on the day before the date of the enactment of this Act, shall*
10 *remain in effect.*