

103^D CONGRESS
1ST SESSION

S. 1597

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

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”.

6 **SEC. 2. 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:

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

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

9 “(A) the planning and conducting of programs
10 to provide information and education to the public
11 on the need for organ donations;

12 “(B) the training of individuals in requesting
13 such donations; or

14 “(C) the provision of technical assistance to
15 organ procurement organizations and other entities
16 in the health care system.

17 “(3)(A) In making awards of grants, cooperative
18 agreements and contracts under subparagraphs (A) and
19 (B) of paragraph (2), the Secretary shall give priority to
20 carrying out the purpose described in such paragraph with
21 respect to minority or other populations for which there
22 is a greater degree of organ shortages relative to the gen-
23 eral population.

24 “(B) In making awards of grants, cooperative agree-
25 ments and contracts under paragraph (2)(C), the Sec-

1 retary shall give priority to carrying out the purpose de-
2 scribed in such paragraph with respect to organ procure-
3 ment organizations and hospitals with lower rates of pro-
4 curement relative to other such organizations or hos-
5 pitals.”.

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

9 (1) in paragraph (1)—

10 (A) in the matter preceding subparagraph
11 (A), by striking “for which grants may be made
12 under subsection (a)” and inserting “described
13 in this section”;

14 (B) by realigning the margin of subpara-
15 graph (E) so as to align with the margin of
16 subparagraph (D); and

17 (C) in subparagraph (G)—

18 (i) in the matter preceding clause (i),
19 by striking “directors or an advisory
20 board” and inserting “directors (or an ad-
21 visory board, in the case of a hospital-
22 based organ procurement organization es-
23 tablished prior to September 1, 1993)”;
24 and

25 (ii) in clause (i)—

1 (I) by striking “composed of” in
2 the matter preceding subclause (I)
3 and inserting “composed of a reason-
4 able balance of”; and

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

13 (2) by striking paragraph (2);

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

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

17 (A) by striking subparagraph (A) and in-
18 serting the following new subparagraph:

19 “(A) with respect to each hospital or other en-
20 tity in its service area that has facilities for organ
21 donations, and except as provided in paragraph
22 (3)—

23 “(i) have in effect an agreement with the
24 entity under which the entity, for the purposes
25 of allocation, identifies potential organ donors

1 and notifies the organ procurement organiza-
2 tion, and

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

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

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

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

18 (D) by inserting before the comma in sub-
19 paragraph (F) (as so redesignated) the follow-
20 ing: “, which system shall, at a minimum, allo-
21 cate each type of organ either on the basis of
22 a single service area list, or an approved alter-
23 nate local unit list (as defined in paragraph
24 (4)), of individuals who have been medically re-
25 ferred to a transplant center in the service area

1 of the organization in order to receive a trans-
2 plant of the type of organ with respect to which
3 the list is maintained”;

4 (E) by striking subparagraph (I) (as so re-
5 designated) and inserting the following new
6 subparagraph:

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

10 (F) by striking subparagraph (K) (as so
11 redesignated) and inserting the following new
12 subparagraph:

13 “(K) evaluate annually, and report to the
14 Organ Procurement and Transplantation Network
15 established under section 372, on the effectiveness of
16 the organization in acquiring potentially available or-
17 gans, particularly among minority populations, and
18 the variation of procurement across hospitals within
19 the organ procurement organization region, and
20 identify a plan to increase procurement, particularly
21 among minority populations and other populations
22 for which there is a greater degree of organ short-
23 ages relative to the general population, and at hos-
24 pitals with low rates of procurement,”; and

1 (G) by adding at the end thereof the fol-
2 lowing flush sentence:

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

7 (5) by adding at the end thereof the following
8 new paragraphs:

9 “(3)(A) The Secretary may waive the requirement
10 that an organ procurement organization have an agree-
11 ment of the type described in paragraph (2)(A) in effect
12 if—

13 “(i)(I) the hospital or other entity within the
14 service area of the organ procurement organization
15 is or seeks to be a party to such an agreement with
16 another organ procurement organization; and

17 “(II) the hospital and organ procurement orga-
18 nization can demonstrate to the satisfaction of the
19 Secretary that their affiliation is based on an agree-
20 ment or understanding between the organ procure-
21 ment organization for the service area in which the
22 hospital is located, and the organ procurement orga-
23 nization with which the hospital desires to affiliate,
24 and such hospital;

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

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

12 “(II) another organ procurement organiza-
13 tion is willing and able to provide such hospital
14 or entity adequate service; or

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

17 “(B) The relationship of a hospital or other entity
18 within the service area of the organ procurement organiza-
19 tion with other organ procurement organizations outside
20 the service area that was in effect as of June 29, 1993,
21 may continue in effect, pending a determination by the
22 Secretary under the waiver process described in subpara-
23 graph (A). Not later than 3 months after the date of en-
24 actment of this paragraph, the hospital or other entity

1 shall notify the Secretary in writing of its intent to proceed
2 with such an existing relationship.

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

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

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

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

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

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

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

1 (A) in clause (i)—

2 (i) by striking “(including organiza-
3 tions that have received grants under sec-
4 tion 371)””; and

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

14 (B) in clause (ii), by inserting “including a
15 patient affairs committee” after “committees,”;
16 (2) in paragraph (2)—

17 (A) by striking clause (A)(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)(F), and”;

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

4 (C) in subparagraph (D), to read as fol-
5 lows:

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

13 (D) by redesignating subparagraphs (E)
14 through (L), as subparagraphs (F) through
15 (M), respectively;

16 (E) by inserting after subparagraph (D),
17 the following new subparagraph:

18 “(E) assist organ procurement organizations in
19 the equitable distribution of organs among trans-
20 plant patients,”;

21 (F) in subparagraph (K) (as so redesi-
22 gnated), by striking “and” at the end thereof;

23 (G) in subparagraph (L) (as so redesi-
24 gnated), by striking the period and inserting “,
25 including making recommendations to organ

1 procurements organizations and the Secretary
2 based on the annual reports required under sec-
3 tion 371(b)(2)(K),”;

4 (H) in subparagraph (M) (as so redesign-
5 dated), by striking the period and inserting a
6 comma; and

7 (I) by adding at the end thereof the follow-
8 ing new subparagraphs:

9 “(N) submit to the Secretary for review and ap-
10 proval any change in the amount of fees imposed by
11 the Network for the registration of individuals on
12 the 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
16 the change is submitted to the Secretary,

17 “(O) make available to the Secretary such in-
18 formation, books, and records regarding the Net-
19 work as the Secretary may require,

20 “(P) submit to the Secretary, on an annual
21 basis, a report on the clinical and scientific status of
22 the organ transplantations, and

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

25 and

1 (3) by adding at the end thereof the following
2 new paragraph:

3 “(3) In carrying out paragraph (2)(D), the Organ
4 Procurement and Transplantation Network shall consult
5 with experts in the area of organ allocation and organ do-
6 nations and consider their recommendations regarding the
7 establishment of regions in the country for the purpose
8 of allocating organs.”.

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

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

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

13 “(a) IN GENERAL.—The Comptroller General of the
14 United States shall conduct a study for the purpose of
15 determining and making recommendations concerning—

16 “(1) the composition of the boards of directors
17 of organ procurement organizations and of the
18 Organ Procurement and Transplantation Network
19 on the date of enactment of this section, and the ef-
20 fect of the Organ Transplant Program Reauthoriza-
21 tion Act of 1993 on the composition and functioning
22 of such boards;

23 “(2)(A) the number and percentage of cadaveric
24 organ transplants for foreign nationals categorized

1 by organ procurement organization and by trans-
2 plant center;

3 “(B) the number and percent of the organiza-
4 tions referred to in subparagraph (A) above the
5 organ procurement transplant network guideline of
6 10 percent; and

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

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

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

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

6 (1) by striking paragraph (2);

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

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

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

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

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

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

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

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

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