

106TH CONGRESS
2D SESSION

S. 2625

AN ACT

To amend the Public Health Service Act to revise the performance standards and certification process for organ procurement organizations.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. ORGAN PROCUREMENT ORGANIZATION CER-**
2 **TIFICATION ACT OF 2000.**

3 (a) FINDINGS.—Congress makes the following find-
4 ings:

5 (1) Organ procurement organizations play an
6 important role in the effort to increase organ dona-
7 tion in the United States.

8 (2) The current process for the certification and
9 recertification of organ procurement organizations
10 conducted by the Department of Health and Human
11 Services has created a level of uncertainty that is
12 interfering with the effectiveness of organ procure-
13 ment organizations in raising the level of organ do-
14 nation.

15 (3) The General Accounting Office, the Insti-
16 tute of Medicine, and the Harvard School of Public
17 Health have identified substantial limitations in the
18 organ procurement organization certification and re-
19 certification process and have recommended changes
20 in that process.

21 (4) The limitations in the recertification process
22 include:

23 (A) An exclusive reliance on population-
24 based measures of performance that do not ac-
25 count for the potential in the population for
26 organ donation and do not permit consideration

1 of other outcome and process standards that
2 would more accurately reflect the relative capa-
3 bility and performance of each organ procure-
4 ment organization.

5 (B) A lack of due process to appeal to the
6 Secretary of Health and Human Services for
7 recertification on either substantive or proce-
8 dural grounds.

9 (5) The Secretary of Health and Human Serv-
10 ices has the authority under section 1138(b)(1)(A)(i)
11 of the Social Security Act (42 U.S.C. 1320b-
12 8(b)(1)(A)(i)) to extend the period for recertification
13 of an organ procurement organization from 2 to 4
14 years on the basis of its past practices in order to
15 avoid the inappropriate disruption of the nation's
16 organ system.

17 (6) The Secretary of Health and Human Serv-
18 ices can use the extended period described in para-
19 graph (5) for recertification of all organ procure-
20 ment organizations to—

21 (A) develop improved performance meas-
22 ures that would reflect organ donor potential
23 and interim outcomes, and to test these meas-
24 ures to ensure that they accurately measure

1 performance differences among the organ pro-
2 curement organizations; and

3 (B) improve the overall certification proc-
4 ess by incorporating process as well as outcome
5 performance measures, and developing equitable
6 processes for appeals.

7 (b) CERTIFICATION AND RECERTIFICATION OF
8 ORGAN PROCUREMENT ORGANIZATIONS.—Section
9 371(b)(1) of the Public Health Service Act (42 U.S.C.
10 273(b)(1)) is amended—

11 (1) by redesignating subparagraphs (D)
12 through (G) as subparagraphs (E) through (H), re-
13 spectively;

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

17 (3) by inserting after subparagraph (C) the fol-
18 lowing:

19 “(D) notwithstanding any other provision of
20 law, has met the other requirements of this section
21 and has been certified or recertified by the Secretary
22 within the previous 4-year period as meeting the
23 performance standards to be a qualified organ pro-
24 curement organization through a process that
25 either—

1 “(i) granted certification or recertification
2 within such 4-year period with such certification
3 or recertification in effect as of January 1,
4 2000, and remaining in effect through the ear-
5 lier of—

6 “(I) January 1, 2002; or

7 “(II) the completion of recertification
8 under the requirements of clause (ii); or

9 “(ii) is defined through regulations that
10 are promulgated by the Secretary by not later
11 than January 1, 2002, that—

12 “(I) require recertifications of quali-
13 fied organ procurement organizations not
14 more frequently than once every 4 years;

15 “(II) rely on outcome and process per-
16 formance measures that are based on em-
17 pirical evidence, obtained through reason-
18 able efforts, of organ donor potential and
19 other related factors in each service area of
20 qualified organ procurement organizations;

21 “(III) use multiple outcome measures
22 as part of the certification process; and

23 “(IV) provide for a qualified organ
24 procurement organization to appeal a de-

1 certification to the Secretary on sub-
2 stantive and procedural grounds;”.

Passed the Senate July 7 (legislative day, July 6),
2000.

Attest:

Secretary.

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