

106TH CONGRESS  
2D SESSION

# H. R. 4592

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

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IN THE HOUSE OF REPRESENTATIVES

JUNE 7, 2000

Mr. CAMP introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Organ Procurement  
5 Organization Certification Act of 2000”.

6 **SEC. 2. ORGAN PROCUREMENT ORGANIZATION CERTIFI-**  
7 **CATION REVISION.**

8 (a) FINDINGS.—Congress makes the following find-  
9 ings:

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

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

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

17          (4) The limitations in the recertification process  
18 include the following:

19               (A) An exclusive reliance on population-  
20 based measures of performance that do not ac-  
21 count for the potential in the population for  
22 organ donation and do not permit consideration  
23 of other outcome and process standards that  
24 would more accurately reflect the relative capa-

1           bility and performance of each organ procure-  
2           ment organization.

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

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

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

19                   (A) develop improved performance meas-  
20                  ures that would reflect organ donor potential  
21                  and interim outcomes, and to test these meas-  
22                  ures to ensure that they accurately measure  
23                  performance differences among the organ pro-  
24                  curement organizations; and

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

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

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

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

15 (3) by inserting after subparagraph (C) the fol-  
16 lowing:

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

24 “(i) granted certification or recertification  
25 within such 4-year period with such certification

1 or recertification in effect as of January 1,  
2 2000, and remaining in effect through the ear-  
3 lier of—

4 “(I) January 1, 2002; or

5 “(II) the completion of recertification  
6 under the requirements of clause (ii); or

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

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

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

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

21 “(IV) provide for a qualified organ  
22 procurement organization to appeal a de-  
23 certification to the Secretary on sub-  
24 stantive and procedural grounds;”.

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