

106TH CONGRESS  
2D SESSION

# H. R. 4152

To amend title XI of the Social Security Act to revise the performance standards and certification process for organ procurement organizations.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 3, 2000

Mr. CAMP (for himself, Mrs. JOHNSON of Connecticut, Mr. PORTMAN, Mr. MATSUI, Mr. PALLONE, and Mr. MOORE) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XI of the Social Security 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. FINDINGS.**

7       The Congress finds as follows:

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 certification and re-  
5 certification 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 organ procurement organization ef-  
9 fectiveness in raising the level of organ donation.

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

16          (4) The limitations in the recertification process  
17 include—

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

1           (B) an immediate decertification of organ  
2 procurement organizations solely on the basis of  
3 the performance measures, without an appropriate  
4 opportunity to file and a grace period to  
5 pursue a corrective action plan; and

6           (C) a lack of due process to appeal to the  
7 Secretary of Health and Human Services for  
8 recertification on either substantive or procedural  
9 grounds.

10          (5) The Secretary of Health and Human Services  
11 has the authority under section  
12 1138(b)(1)(A)(ii) of the Social Security Act to extend  
13 the period for recertification of an organ procurement  
14 organization from 2 to 4 years on the  
15 basis of its past practices in order to avoid the inappropriate  
16 disruption of the Nation's organ system.

17          (6) The Secretary of Health and Human Services  
18 can use the extended period for recertification  
19 of all organ procurement organizations to—

20           (A) develop improved performance measures  
21 that would reflect organ donor potential  
22 and interim outcomes, and to test these measures  
23 to ensure that they accurately measure  
24 performance differences among the organ procurement  
25 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 corrective action plans and ap-  
5 peals.

6 **SEC. 3. CERTIFICATION AND RECERTIFICATION OF ORGAN**  
7 **PROCUREMENT ORGANIZATIONS.**

8 (a) IN GENERAL.—Section 1138(b) of the Social Se-  
9 curity Act (42 U.S.C. 1320b–8(b)) is amended—

10 (1) in paragraph (1)(A)(ii) by striking “within  
11 the previous 2 years (4 years if the Secretary deter-  
12 mines appropriate for an organization on the basis  
13 of its past practices) as meeting the standards to be  
14 a qualified organ procurement organization (as so  
15 described);” and inserting “under paragraph (2)  
16 within the previous 4 years;”;

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

19 (3) by inserting after paragraph (1) the fol-  
20 lowing new paragraph:

21 “(2) Not later than January 1, 2002, the Secretary  
22 shall set forth in regulations the process and performance  
23 standards by which an organization shall be certified or  
24 recertified as a qualified organ procurement organization  
25 consistent with the following:

1           “(A) Certification or recertification of such an  
2 organization shall be made not more frequently than  
3 once every 4 years.

4           “(B) Performance standards applicable for cer-  
5 tification or recertification of an organization shall  
6 use—

7                   “(i) outcome and process performance  
8 measures that are based on empirical evidence  
9 of organ donor potential and other related fac-  
10 tors in each service area of qualified organ pro-  
11 curement organizations, and

12                   “(ii) multiple outcome measures, which  
13 may or may not be based on empirical evidence.

14           “(C)(i) In the case of a certified qualified organ  
15 procurement organization that the Secretary deter-  
16 mines does not meet the performance standards for  
17 recertification, the organization may submit to the  
18 Secretary a corrective action plan.

19                   “(ii) If the Secretary approves the corrective ac-  
20 tion plan submitted under clause (i), the Secretary  
21 shall provide for an additional 3-year period during  
22 which such organization shall implement the correc-  
23 tive action plan. An organization implementing a  
24 corrective action plan shall be treated as being cer-  
25 tified by the Secretary during such 3-year period.

1 The Secretary shall develop and implement appropriate  
2 procedures for an organization to appeal a decision of the  
3 Secretary to deny certification or recertification of an or-  
4 ganization under this paragraph.”.

5 (b) TRANSITION RULE.—In the case of an organiza-  
6 tion that on January 1, 2000, has in effect a certification  
7 or recertification by the Secretary of Health and Human  
8 Services as a qualified organ procurement organization  
9 under section 1138(b)(1)(A)(ii) of the Social Security Act  
10 (42 U.S.C. 1320b–8(b)(1)(A)(ii)), such certification or re-  
11 certification shall remain in effect until the earlier of Jan-  
12 uary 1, 2002, or the date on which the Secretary publishes  
13 a final rule implementing the provisions of 1138(b)(2), as  
14 added by subsection (a) of this Act.

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