

106TH CONGRESS  
2D SESSION

# S. 2235

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 9, 2000

Ms. COLLINS (for herself, Mr. MURKOWSKI, Mr. DODD, Mr. TORRICELLI, and Mr. HUTCHINSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Public Health 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       Congress makes the following findings:

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:

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) An immediate decertification of organ  
4           procurement organizations solely on the basis of  
5           the performance measures, without an appro-  
6           priate opportunity to file and a grace period to  
7           pursue a corrective action plan.

8           (C) A lack of due process to appeal to the  
9           Secretary of Health and Human Services for  
10          recertification on either substantive or proce-  
11          dural grounds.

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

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

24                  (A) develop improved performance meas-  
25                  ures that would reflect organ donor potential

and interim outcomes, and to test these measures to ensure that they accurately measure performance differences among the organ procurement organizations; and

(B) improve the overall certification process by incorporating process as well as outcome performance measures, and developing equitable processes for corrective action plans and appeals.

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

Section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) is amended:

(1) by redesignating subparagraphs (D) through (G) as subparagraphs (E) through (H), respectively;

(2) by realigning the margin of subparagraph (F) (as so redesignated) so as to align with subparagraph (E) (as so redesignated); and

(3) by inserting after subparagraph (C) the following:

“(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the

1 performance standards to be a qualified organ pro-  
2 curement organization through a process that  
3 either—

4 “(i) granted certification or recertification  
5 within such 4-year period with such certification  
6 or recertification in effect as of January 1,  
7 2000, and remaining in effect through the ear-  
8 lier of—

9 “(I) January 1, 2002; or

10 “(II) the completion of recertification  
11 under the requirements of clause (ii); or

12 “(ii) is defined through regulations that  
13 are promulgated by the Secretary by not later  
14 than January 1, 2002, that—

15 “(I) require recertifications of quali-  
16 fied organ procurement organizations not  
17 more frequently than once every 4 years;

18 “(II) rely on outcome and process per-  
19 formance measures that are based on em-  
20 pirical evidence of organ donor potential  
21 and other related factors in each service  
22 area of qualified organ procurement orga-  
23 nizations;

24 “(III) use multiple outcome measures  
25 as part of the certification process;

1           “(IV) provide for the filing and ap-  
2           proval of a corrective action plan by a  
3           qualified organ procurement organization  
4           that fails to meet the performance stand-  
5           ards and a grace period of not less than 3  
6           years during which such organization can  
7           implement the corrective action plan with-  
8           out risk of decertification; and

9           “(V) provide for a qualified organ  
10          procurement organization to appeal a de-  
11          certification to the Secretary on sub-  
12          stantive and procedural grounds;”.

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