

107<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 3504

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## AN ACT

To amend the Public Health Service Act with respect to  
qualified 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 That section 371(b)(1) of the Public Health Service Act

1 (42 U.S.C. 273(b)(1)) is amended by striking subpara-  
2 graph (D) and all that follows and inserting the following:

3           “(D) notwithstanding any other provision of  
4 law, has met the other requirements of this section  
5 and has been certified or recertified by the Secretary  
6 as meeting the performance standards to be a quali-  
7 fied organ procurement organization through a proc-  
8 ess that granted certification or recertification with  
9 such certification or recertification in effect as of  
10 January 1, 2000, and remaining in effect through  
11 the completion of certification or recertification, no  
12 earlier than July 31, 2004, as is defined through  
13 regulations that are promulgated by the Secretary  
14 that—

15           “(i) require recertifications of qualified  
16 organ procurement organizations not more fre-  
17 quently than once every 4 years,

18           “(ii) rely on outcome and process perform-  
19 ance measures that are based on empirical evi-  
20 dence, obtained through reasonable efforts, of  
21 organ donor potential and other related factors  
22 in each service area of qualified organ procure-  
23 ment organizations,

24           “(iii) use multiple outcome measures as  
25 part of the certification process, and

1           “(iv) provide for a qualified organ procure-  
2           ment organization to appeal a decertification to  
3           the Secretary on substantive and procedural  
4           grounds,

5           “(E) has procedures to obtain payment for non-  
6           renal organs provided to transplant centers,

7           “(F) has a defined service area that is of suffi-  
8           cient size to assure maximum effectiveness in the  
9           procurement and equitable distribution of organs,  
10          and that either includes an entire metropolitan sta-  
11          tistical area (as specified by the Director of the Of-  
12          fice of Management and Budget) or does not include  
13          any part of the area,

14          “(G) has a director and such other staff, in-  
15          cluding the organ donation coordinators and organ  
16          procurement specialists necessary to effectively ob-  
17          tain organs from donors in its service area, and

18          “(H) has a board of directors or an advisory  
19          board which—

20                  “(i) is composed of—

21                          “(I) members who represent hospital  
22                          administrators, intensive care or emer-  
23                          gency room personnel, tissue banks, and  
24                          voluntary health associations in its service  
25                          area,

1                   “(II) members who represent the pub-  
2                   lic residing in such area,

3                   “(III) a physician with knowledge, ex-  
4                   perience, or skill in the field of  
5                   histocompatibility or an individual with a  
6                   doctorate degree in a biological science  
7                   with knowledge, experience, or skill in the  
8                   field of histocompatibility,

9                   “(IV) a physician with knowledge or  
10                  skill in the field of neurology, and

11                  “(V) from each transplant center in  
12                  its service area which has arrangements  
13                  described in paragraph (3)(G) with the or-  
14                  ganization, a member who is a surgeon  
15                  who has practicing privileges in such cen-  
16                  ter and who performs organ transplant  
17                  surgery,

18                  “(ii) has the authority to recommend poli-  
19                  cies for the procurement of organs and the  
20                  other functions described in paragraph (3), and

1                   “(iii) has no authority over any other ac-  
2                   tivity of the organization.”.

Passed the House of Representatives December 20,  
2001.

Attest:

*Clerk.*



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