

108TH CONGRESS  
2D SESSION

# S. 2880

To amend title XI of the Social Security Act to ensure full and free competition in the medical device and hospital supply industries.

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IN THE SENATE OF THE UNITED STATES

OCTOBER 1, 2004

Mr. KOHL (for himself and Mr. DEWINE) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To amend title XI of the Social Security Act to ensure full and free competition in the medical device and hospital supply industries.

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 “Medical Device Com-  
5       petition Act of 2004”.

6       **SEC. 2. FINDINGS.**

7       Congress finds the following:

8               (1) Given the increasing costs of health care in  
9       the United States, there is a compelling public inter-  
10      est in ensuring that there is full and free competi-

1       tion in the medical device and hospital supply indus-  
2       tries so that the best and safest products are avail-  
3       able to physicians and patients at a competitive  
4       price.

5           (2) By aggregating purchases, hospital group  
6       purchasing can reduce the cost of acquiring medical  
7       equipment and hospital supplies so long as such pur-  
8       chasing is done in a manner consistent with anti-  
9       trust law and free competition.

10          (3) Some practices engaged in by certain hos-  
11       pital group purchasing organizations have had the  
12       effect of reducing competition in the medical device  
13       and hospital supply industries by denying some sup-  
14       pliers and device makers access to the hospital mar-  
15       ketplace.

16          (4) There is a compelling public interest in hav-  
17       ing the Secretary of Health and Human Services, in  
18       consultation with the Attorney General and Federal  
19       Trade Commission, engage in oversight and super-  
20       vision of the current Federal health care program  
21       anti-kickback exemption (also known as the safe  
22       harbor) provided to group purchasing organizations  
23       under subparagraphs (C) and (E) of section  
24       1128B(b)(3) of the Social Security Act (42 U.S.C.  
25       1320a-7b(b)(3)). This oversight and supervision

1       should ensure that the safe harbor does not shield  
 2       conduct that harms competition in the hospital sup-  
 3       ply and medical device industries.

4   **SEC. 3. ENSURING FULL AND FREE COMPETITION.**

5       (a) IN GENERAL.—Section 1128B(b)(3)(C) of the  
 6   Social Security Act (42 U.S.C. 1320a–7b(b)(3)(C)) is  
 7   amended—

8           (1) in clause (i), by striking “, and” at the end  
 9       and inserting a semicolon; and

10          (2) by adding at the end the following new  
 11       clauses:

12                   “(iii) the contracting, business, and  
 13                   ethical practices of the person are not in-  
 14                   consistent with regulations promulgated by  
 15                   the Secretary pursuant to subsection  
 16                   (g)(1);

17                   “(iv) the person has been certified by  
 18                   the Secretary under subsection (g)(2) to be  
 19                   in compliance with the regulations promul-  
 20                   gated pursuant to subsection (g)(1); and

21                   “(v) the amount to be paid the person  
 22                   does not exceed a total of 3 percent of the  
 23                   purchase price of the goods or services pro-  
 24                   vided by that vendor;”.

1 (b) REGULATIONS.—Section 1128B of the Social Se-  
2 curity Act (42 U.S.C. 1320a–7b) is amended by adding  
3 at the end the following new subsection:

4 “(g)(1)(A) The Secretary, in consultation with the  
5 Attorney General and the Federal Trade Commission,  
6 shall, not later than 1 year after the date of enactment  
7 of the Medical Device Competition Act of 2004, issue pro-  
8 posed regulations, and shall, not later than 2 years after  
9 such date of enactment, promulgate final regulations,  
10 specifying contracting, business, and ethical practices of  
11 persons described in paragraph (4) that are contrary to  
12 antitrust law and competitive principles, to ethical stand-  
13 ards, or to the goal of ensuring that products necessary  
14 for proper patient care or worker safety are readily avail-  
15 able to physicians, health care workers, and patients.

16 “(B) In issuing and promulgating regulations under  
17 subparagraph (A), the Secretary shall take into account—

18 “(i) the compelling public policy goals of—

19 “(I) encouraging competition and innova-  
20 tion in the hospital supply and medical device  
21 markets; and

22 “(II) reducing the cost of health care as a  
23 result of aggregating buying power;

24 “(ii) the potentially detrimental impact of cer-  
25 tain anticompetitive contracting practices; and

1           “(iii) the need to avoid conflicts of interests and  
2           other unethical practices by persons described in  
3           paragraph (4).

4           “(2) The Secretary, in consultation with the Attorney  
5           General and the Federal Trade Commission, shall estab-  
6           lish procedures for annually certifying that persons de-  
7           scribed in paragraph (4) are in compliance with the final  
8           regulations promulgated pursuant to paragraph (1).

9           “(3) The Secretary, in consultation with the Attorney  
10          General and Federal Trade Commission, shall, not less  
11          than 6 months after the date of enactment of the Medical  
12          Device Competition Act of 2004, issue proposed regula-  
13          tions, and shall, not later than 1 year after such date of  
14          enactment, promulgate final regulations, to clarify its reg-  
15          ulations promulgated pursuant to section 14(a) of the  
16          Medicare and Medicaid Patient and Program Protection  
17          Act of 1987 to specify that the definition of ‘remuneration’  
18          under this section with respect to persons described in  
19          paragraph (4)—

20                 “(A) includes only those reasonable costs asso-  
21                 ciated with the procurement of products and the ad-  
22                 ministration of valid contracts; and

23                 “(B) does not include marketing costs, any ex-  
24                 traneous fees, or any other payment intended to un-  
25                 duly or improperly influence the award of a contract

1       based on factors other than the cost, quality, safety,  
2       or efficacy of the product.

3       “(4) A person described in this paragraph is a person  
4 authorized to act as a purchasing agent for a group of  
5 individuals or entities who are furnishing services reim-  
6 bursable under a Federal health care program.”.

7       (c) DEFINITION OF PURCHASING AGENT.—Section  
8 1128B of the Social Security Act (42 U.S.C. 1320a–7b),  
9 as amended by subsection (b), is amended by adding at  
10 the end the following new subsection:

11       “(h) For purposes of this section, the term ‘pur-  
12 chasing agent’ means any individual, organization, or  
13 other entity that negotiates and implements contracts to  
14 purchase hospital supplies or medical equipment, devices,  
15 products, or goods or services of any kind for any group  
16 of individuals or entities who are furnishing services reim-  
17 bursable under a Federal health care program, including  
18 organizations commonly known as ‘group purchasing or-  
19 ganizations’.”.

20       (d) EFFECTIVE DATE.—Clause (v) of section  
21 1128B(b)(3)(C) of the Social Security Act (42 U.S.C.  
22 1320a–7b(b)(3)(C)), as added by subsection (a), shall take  
23 effect 1 year after the date of enactment of this Act.

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