108TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

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

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Device Competition Act of 2004''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Given the increasing costs of health care in the United States, there is a compelling public inter-

est in ensuring that there is full and free competition in the medical device and hospital supply industries so that the best and safest products are available to physicians and patients at a competitive price.

(2) By aggregating purchases, hospital group purchasing can reduce the cost of acquiring medical equipment and hospital supplies so long as such purchasing is done in a manner consistent with antitrust law and free competition.

(3) Some practices engaged in by certain hospital group purchasing organizations have had the effect of reducing competition in the medical device and hospital supply industries by denying some suppliers and device makers access to the hospital marketplace.

(4) There is a compelling public interest in having the Secretary of Health and Human Services, in consultation with the Attorney General and Federal Trade Commission, engage in oversight and supervision of the current Federal health care program anti-kickback exemption (also known as the safe harbor) provided to group purchasing organizations under subparagraphs (C) and (E) of section 1128B(b)(3) of the Social Security Act (42 U.S.C.

1320a–7b(b)(3)). This oversight and supervision should ensure that the safe harbor does not shield conduct that harms competition in the hospital supply and medical device industries.

SEC. 3. ENSURING FULL AND FREE COMPETITION.

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

(1) in clause (i), by striking ", and" at the end and inserting a semicolon; and

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

"(iii) the contracting, business, and ethical practices of the person are not inconsistent with regulations promulgated by the Secretary pursuant to subsection (g)(1);

"(iv) the person has been certified by the Secretary under subsection (g)(2) to be in compliance with the regulations promulgated pursuant to subsection (g)(1); and

"(v) the amount to be paid the person does not exceed a total of 3 percent of the purchase price of the goods or services provided by that vendor;".

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

''(g)(1)(A) The Secretary, in consultation with the Attorney General and the Federal Trade Commission, shall, not later than 1 year after the date of enactment of the Medical Device Competition Act of 2004, issue proposed regulations, and shall, not later than 2 years after such date of enactment, promulgate final regulations, specifying contracting, business, and ethical practices of persons described in paragraph (4) that are contrary to antitrust law and competitive principles, to ethical standards, or to the goal of ensuring that products necessary for proper patient care or worker safety are readily available to physicians, health care workers, and patients.

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

''(i) the compelling public policy goals of—

''(I) encouraging competition and innovation in the hospital supply and medical device markets; and

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

''(ii) the potentially detrimental impact of certain anticompetitive contracting practices; and

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

''(2) The Secretary, in consultation with the Attorney General and the Federal Trade Commission, shall establish procedures for annually certifying that persons described in paragraph (4) are in compliance with the final regulations promulgated pursuant to paragraph (1).

''(3) The Secretary, in consultation with the Attorney General and Federal Trade Commission, shall, not less than 6 months after the date of enactment of the Medical Device Competition Act of 2004, issue proposed regulations, and shall, not later than 1 year after such date of enactment, promulgate final regulations, to clarify its regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 to specify that the definition of 'remuneration' under this section with respect to persons described in paragraph (4)—

''(A) includes only those reasonable costs associated with the procurement of products and the administration of valid contracts; and

''(B) does not include marketing costs, any extraneous fees, or any other payment intended to unduly or improperly influence the award of a contract

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

''(4) A person described in this paragraph is a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursable under a Federal health care program.''.

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

''(h) For purposes of this section, the term 'purchasing agent' means any individual, organization, or other entity that negotiates and implements contracts to purchase hospital supplies or medical equipment, devices, products, or goods or services of any kind for any group of individuals or entities who are furnishing services reimbursable under a Federal health care program, including organizations commonly known as 'group purchasing organizations'.''.

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