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.
 - 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 in9 the United States, there is a compelling public inter-

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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.

6 (2) By aggregating purchases, hospital group 7 purchasing can reduce the cost of acquiring medical 8 equipment and hospital supplies so long as such pur-9 chasing is done in a manner consistent with anti-10 trust 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.

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

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1	1320a-7b(b)(3)). This oversight and supervision
2	should ensure that the safe harbor does not shield
3	conduct that harms competition in the hospital sup-
4	ply and medical device industries.
5	SEC. 3. ENSURING FULL AND FREE COMPETITION.
6	(a) IN GENERAL.—Section $1128B(b)(3)(C)$ of the
7	Social Security Act (42 U.S.C. $1320a-7b(b)(3)(C)$) is
8	amended—
9	(1) in clause (i), by striking ", and" at the end
10	and inserting a semicolon; and
11	(2) by adding at the end the following new
12	clauses:
13	"(iii) the contracting, business, and
14	ethical practices of the person are not in-
15	consistent with regulations promulgated by
16	the Secretary pursuant to subsection
17	(g)(1);
18	"(iv) the person has been certified by
19	the Secretary under subsection $(g)(2)$ to be
20	in compliance with the regulations promul-
21	gated pursuant to subsection $(g)(1)$; and
22	"(v) the amount to be paid the person
23	does not exceed a total of 3 percent of the
24	purchase price of the goods or services pro-
25	vided by that vendor;".

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(b) REGULATIONS.—Section 1128B of the Social Se curity Act (42 U.S.C. 1320a–7b) is amended by adding
 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, shall, not later than 1 year after the date of enactment 6 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 persons described in paragraph (4) that are contrary to 11 12 antitrust law and competitive principles, to ethical stand-13 ards, or to the goal of ensuring that products necessary for proper patient care or worker safety are readily avail-14 15 able to physicians, health care workers, and patients.

16 "(B) In issuing and promulgating regulations under17 subparagraph (A), the Secretary shall take into account—

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

19 "(I) encouraging competition and innova20 tion in the hospital supply and medical device
21 markets; and

22 "(II) reducing the cost of health care as a23 result of aggregating buying power;

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

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

4 "(2) The Secretary, in consultation with the Attorney
5 General and the Federal Trade Commission, shall estab6 lish procedures for annually certifying that persons de7 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 than 6 months after the date of enactment of the Medical 11 Device Competition Act of 2004, issue proposed regula-12 13 tions, and shall, not later than 1 year after such date of enactment, promulgate final regulations, to clarify its reg-14 15 ulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection 16 Act of 1987 to specify that the definition of 'remuneration' 17 18 under this section with respect to persons described in 19 paragraph (4)—

20 "(A) includes only those reasonable costs asso21 ciated with the procurement of products and the ad22 ministration of valid contracts; and

23 "(B) does not include marketing costs, any ex24 traneous fees, or any other payment intended to un25 duly or improperly influence the award of a contract

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based on factors other than the cost, quality, safety,
 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 reim6 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 purchase hospital supplies or medical equipment, devices, 14 15 products, or goods or services of any kind for any group of individuals or entities who are furnishing services reim-16 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.