110TH CONGRESS
1ST SESSION

S. _____

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

IN THE SENATE OF THE UNITED STATES

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

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A BILL

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

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 ''Physician Payments Sunshine Act of 2007''.

SEC. 2. QUARTERLY TRANSPARENCY REPORTS FROM MANUFACTURERS OF COVERED DRUGS, DEVICES, OR MEDICAL SUPPLIES UNDER MEDICARE, MEDICAID, OR SCHIP.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128F the following new section:

"SEC. 1128G. QUARTERLY TRANSPARENCY REPORTS FROM MANUFACTURERS OF COVERED DRUGS, DEVICES, OR MEDICAL SUPPLIES UNDER MEDICARE, MEDICAID, OR SCHIP.

''(a) REPORTING OF PAYMENTS OR OTHER TRANSFER OF VALUE.—On January 1, 2008, and the first day of each fiscal year quarter beginning thereafter, each manufacturer of a covered drug, device, or medical supply who provides a payment or other transfer of value, directly, indirectly, or through an agent, subsidiary, or other third party, to a physician, or to an entity that a physician is employed by, has tenure with, or has an ownership interest in, shall submit to the Secretary, in such electronic form as the Secretary shall require, the following:

''(1) The name of the physician, and if a payment or other transfer of value was provided to an entity that the physician is employed by, has tenure with, or has an ownership interest in, the entity.

''(2) The address of—

''(A) the physician's office; and

''(B) in the case of an entity required to be named under paragraph (1), the primary place of business or headquarters for the entity.

''(3) The facility with which the physician is affiliated, if any.

''(4) The value of the payment or other transfer of value.

''(5) The date on which the payment or other transfer of value was provided.

''(6) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

''(A) compensation;

''(B) food, entertainment, or gifts;

''(C) trips or travel;

''(D) a product or other item provided for less than market value;

''(E) participation in a medical conference, continuing medical education, or other educational or informational program or seminar, provision of materials related to such a conference or educational or informational program or seminar, or remuneration for promoting or

participating in such a conference or educational or informational program or seminar;

"(F) product rebates or discounts;

"(G) consulting fees or honoraria; or

"(H) any other economic benefit, as defined by the Secretary.

"(7) The medical issue or condition addressed, if any, that was the basis for the payment or transfer.

"(b) ANNUAL SUMMARY REPORT.—Each manufacturer of a covered drug, device, or medical supply that is required to submit information under subsection (a) during a year shall submit a report to the Secretary not later than December 31 of the year that summarizes, in such electronic form as the Secretary shall specify, each submission of information under subsection (a) made by the manufacturer during the year.

"(c) PENALTY FOR NONCOMPLIANCE.—Any manufacturer of a covered drug, device, or medical supply that fails to submit information required under subsection (a) or (b) in accordance with regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each such failure. Such penalty shall be imposed and collected in the same manner as civil money

penalties under subsection (a) of section 1128A are imposed and collected under that section.

''(d) PUBLIC AVAILABILITY.—Not later than June 1, 2008, the Secretary shall establish procedures to ensure that the information reported under subsection (a) and the summary reports submitted under subsection (b) are readily accessible to the public through an Internet website that is easily searchable, downloadable, and understandable.

''(e) REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2009, the Secretary shall submit to Congress a report that includes the following:

''(1) The information submitted under subsections (a) and (b) during the preceding year, aggregated for each manufacturer of a covered drug, device, or medical supply that submitted such information during such year.

''(2) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (c), during the preceding year.

''(f) DEFINITIONS.—In this section:

''(1) COVERED DRUG, DEVICE, OR MEDICAL SUPPLY.—The term 'covered drug, device, or medical supply' means any drug, biological product, de-

vice, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

''(2) MANUFACTURER OF A COVERED DRUG, DEVICE, OR MEDICAL SUPPLY.—The term 'manufacturer of a covered drug, device, or medical supply' means any entity with annual gross revenues that exceed $100,000,000, which is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a covered drug, device, or medical supply; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a covered drug, device, or medical supply.

''(3) PAYMENT OR OTHER TRANSFER OF VALUE.—

''(A) IN GENERAL.—The term 'payment or other transfer of value' means a transfer of anything of value that exceeds $25, and includes any compensation, gift, honorarium, speaking fee, consulting fee, travel, discount, cash rebate, or services.

''(B) EXCLUSIONS.—Such term does not include the following:

"(i) Product samples that are intended for patients.

"(ii) A payment or other transfer of value made for the general funding of a clinical trial.

"(iii) A transfer of anything of value to a physician when the physician is a patient and not acting in his or her professional capacity.

"(4) PHYSICIAN.—The term 'physician' has the meaning given that term in section 1861(r).".