111TH CONGRESS
1ST SESSION

S. 301

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

IN THE SENATE OF THE UNITED STATES

JANUARY 22, 2009

Mr. GRASSLEY (for himself, Mr. KOHL, and Ms. KLOBUCHAR) 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 provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, 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 2009''.

SEC. 2. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

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. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

"(a) TRANSPARENCY REPORTS.—

"(1) PAYMENTS OR OTHER TRANSFERS OF VALUE.—

"(A) IN GENERAL.—Except as provided in subsection (e), on March 31, 2011, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

"(i) The name of the covered recipient.

''(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and Medicare billing number of the covered recipient.

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

''(iv) The dates on which the payment or other transfer of value was provided to the covered recipient.

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

''(I) cash or a cash equivalent;

''(II) in-kind items or services;

''(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

''(IV) any other form of payment or other transfer of value (as defined by the Secretary).

''(vi) A description of the nature of the payment or other transfer of value, in-

dicated (as appropriate for all that apply) as—

''(I) consulting fees;

''(II) compensation for services other than consulting;

''(III) honoraria;

''(IV) gift;

''(V) entertainment;

''(VI) food;

''(VII) travel;

''(VIII) education;

''(IX) research;

''(X) charitable contribution;

''(XI) royalty or license;

''(XII) current or prospective ownership or investment interest;

''(XIII) compensation for serving as faculty or as a speaker for a continuing medical education program;

''(XIV) grant; or

''(XV) any other nature of the payment or other transfer of value (as defined by the Secretary).

''(vii) If the payment or other transfer of value is related to marketing, education,

or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

''(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

''(B) AGGREGATE REPORTING.—Information submitted by an applicable manufacturer under subparagraph (A) shall include the aggregate amount of all payments or other transfers of value provided by the applicable manufacturer to covered recipients (and to entities or individuals at the request of or designated on behalf of a covered recipient) during the preceding year.

''(C) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that pay-

ment or other transfer of value under the name of the covered recipient.

''(2) PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (1)(A), on March 31, 2011, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

''(A) The dollar amount invested by each physician holding such an ownership or investment interest.

''(B) The value and terms of each such ownership or investment interest.

''(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an enti-

ty or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, 'physician' shall be substituted for 'covered recipient' each place it appears.

''(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

''(b) PENALTIES FOR NONCOMPLIANCE.—

''(1) FAILURE TO REPORT.—

''(A) IN GENERAL.—Subject to subparagraph (B), except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. 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.

''(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $150,000.

''(2) KNOWING FAILURE TO REPORT.—

''(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or 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 payment or other transfer of value or ownership or investment interest not reported as required under such subsection. 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.

''(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.

''(3) USE OF FUNDS.—Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

''(c) PROCEDURES FOR SUBMISSION OF INFORMATION AND PUBLIC AVAILABILITY.—

''(1) IN GENERAL.—

''(A) ESTABLISHMENT.—Not later than November 1, 2009, the Secretary shall establish procedures—

''(i) for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary under subsection (a); and

"(ii) for the Secretary to make such information submitted available to the public.

"(B) DEFINITION OF TERMS.—The procedures established under subparagraph (A) shall provide for the definition of terms (other than those terms defined in subsection (g)), as appropriate, for purposes of this section.

"(C) PUBLIC AVAILABILITY.—The procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2011, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that—

"(i) is searchable and is in a format that is clear and understandable;

"(ii) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other

transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

''(iii) contains information that is able to be easily aggregated and downloaded;

''(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

''(v) contains background information on industry-physician relationships;

''(vi) in the case of information submitted with respect to a payment or other transfer of value described in subsection (e), lists such information separately from the other information submitted under subsection (a) and designates such sepa-

rately listed information as funding for clinical research;

''(vii) contains any other information the Secretary determines would be helpful to the average consumer; and

''(viii) provides the covered recipient an opportunity to submit corrections to the information made available to the public with respect to the covered recipient.

''(2) CONSULTATION.—In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

''(d) ANNUAL REPORTS AND RELATION TO STATE LAWS.—

''(1) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2011, the Secretary shall submit to Congress a report that includes the following:

''(A) The information submitted under subsection (a) during the preceding year, aggre-

gated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year.

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

''(2) ANNUAL REPORTS TO STATES.—Not later than April 1 of each year beginning with 2011, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State.

''(3) RELATION TO STATE LAWS.—

''(A) IN GENERAL.—Effective on January 1, 2010, subject to subparagraph (B), the provisions of this section shall preempt any law or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as defined in subsection (g)) to disclose or report information (as described in subsection (a)) regarding a payment or other transfer of value provided by the applicable manufacturer to a covered recipient (as so described).

''(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Subparagraph (A) shall not preempt any law or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information not required to be disclosed or reported under this section.

''(e) DELAYED REPORTING FOR PAYMENTS MADE PURSUANT TO PRODUCT DEVELOPMENT AGREEMENTS AND CLINICAL INVESTIGATIONS.—In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product development agreement for services furnished in connection with the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation, the applicable manufacturer may report the value of such payment or other transfer of value in the first reporting period under subsection (a) after the earlier of the following:

''(1) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

''(2) Two calendar years after the date such payment or other transfer of value was made.

''(f) IMPLEMENTATION.—

''(1) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

''(2) LIMITATION ON REVIEW.—There shall be no judicial review of the implementation of this section.

''(g) DEFINITIONS.—In this section:

''(1) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply.

''(2) APPLICABLE MANUFACTURER.—The term 'applicable manufacturer' means a manufacturer of a covered drug, device, biological, or medical supply.

''(3) CLINICAL INVESTIGATION.—The term 'clinical investigation' means any experiment involving 1 or more human subjects in which a drug or device is administered, dispensed, or used.

''(4) COVERED DEVICE.—The term 'covered device' means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

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

''(6) COVERED RECIPIENT.—The term 'covered recipient' means the following:

''(A) A physician.

''(B) A physician medical practice.

''(C) A physician group practice.

''(7) EMPLOYEE.—The term 'employee' has the meaning given such term in section 1877(h)(2).

''(8) KNOWINGLY.—The term 'knowingly' has the meaning given such term in section 3729(b) of title 31, United States Code.

''(9) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term 'manufacturer of a covered drug, device, biological, or medical supply' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, processing, marketing, or distribution of a covered drug, device, biological, or

medical supply (or any subsidiary of or entity affiliated with such entity).

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

''(A) IN GENERAL.—The term 'payment or other transfer of value' means a transfer of anything of value and includes, subject to subparagraph (B), without limitation, any compensation, gift, honorarium, speaking fee, consulting fee, travel, services, dividend, profit distribution, stock or stock option grant, or ownership or investment interest.

''(B) EXCLUSIONS.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

''(i) Any payment or other transfer of value provided by an applicable manufacturer to a covered recipient where the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient does not exceed $100 during the calendar year. Such aggregate amount shall be determined without taking into ac-

count any payment or other transfer of value described in clauses (ii) through (ix).

''(ii) Product samples that are not intended to be sold and are intended for patient use.

''(iii) Educational materials that directly benefit patients or are intended for patient use.

''(iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

''(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

''(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

''(vii) Discounts (including rebates).

''(viii) In-kind items used for the provision of charity care.

"(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

"(11) PHYSICIAN.—The term 'physician' has the meaning given that term in section 1861(r). For purposes of this section, such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).".

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