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110TH CONGRESS
2D SESSION

H. R. 5605

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, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2008

Mr. DEFAZIO (for himself, Mr. STARK, Mr. BERRY, Mr. CHANDLER, Mr. MORAN of Virginia, Mr. HINCHEY, Mr. MCGOVERN, Mr. ISRAEL, Mr. DOGGETT, Ms. LEE, Mr. WU, and Mr. KUCINICH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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, and for other purposes.

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 2008''.

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, 2009, 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; to an entity that a physician is employed by, has tenure with, or has a significant ownership interest in; or to a covered organization in which a physician has a significant professional membership interest, shall submit to the Secretary, in such electronic form as the Secretary shall require, the following:

''(1) The name of—

''(A) the physician;

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

''(C) if a payment or other transfer of value was provided to an organization so specified in which the physician has such a significant professional membership interest, the name of the organization.

''(2) The address of—

''(A) the physician's office;

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

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

''(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, other educational or informational program or seminar, or funded research (such as lab-based, epidemiology, or health services research) that is not a clinical trial; provision of materials related to such a conference, educational or informational program or seminar, or research; or remuneration for promoting or participating in such a conference, educational or informational program or seminar, or research;

''(F) product rebates or discounts;

''(G) consulting fees or honoraria;

"(H) dividend, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in a manufacturer (excluding 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)); or

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

"(7) The purpose of the expenditure according to categories specified by the Secretary, such as consulting, education, royalty, and research.

"(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. The summary report shall include the aggregate amount of all transfers of anything of value that is less than $25, including any compensation, gift, honorarium, speaking fee, consulting fee, travel, discount, cash rebate, or services.

''(c) REPORTING DATE FOR APPLICABLE CLINICAL TRIALS.—

''(1) IN GENERAL.—Notwithstanding subsection (a), a payment or other transfer of value made for the general funding of a clinical trial described in paragraph (2) shall be disclosed in the first quarterly report after the date clinical trial information for such trial is required to be posted under section 402(j)(2)(D) of the Public Health Service Act.

''(2) CLINICAL TRIAL.—A clinical trial described in this paragraph is an applicable clinical trial for which clinical trial information is required to be submitted under section 402(j)(2)(C) of the Public Health Service Act.

''(d) PENALTY FOR NONCOMPLIANCE.—Any manufacturer of a covered drug, device, or medical supply that knowingly 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.

''(e) PUBLIC AVAILABILITY.—Not later than June 1, 2009, 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.

''(f) REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2010, 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 (d), during the preceding year.

''(g) DEFINITIONS.—In this section:

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

able under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

''(2) COVERED ORGANIZATION.—The term 'covered organization' means an organization that is involved in health care financing, organization, or delivery.

''(3) MANUFACTURER OF A COVERED DRUG, DEVICE, OR MEDICAL SUPPLY.—The term 'manufacturer of a covered drug, device, or medical supply' means any entity—

''(A) with annual gross revenues that exceed $1,000,000; and

''(B) which is engaged in the production, preparation, propagation, compounding, conversion, or processing of a covered drug, device, or medical supply.

''(4) 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, services, or dividend, profit distribution, stock or stock option grant, or any

ownership or investment interest held by a physician in a manufacturer (excluding a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund (as described in section 1877(c)).

''(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, other than an applicable clinical trial for which clinical trial information is required to be submitted under section 402(j)(2)(C) of the Public Health Service Act.

''(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.

''(iv) Compensation paid by a manufacturer of a covered drug, device, or medical supply to a physician who is directly

employed by and works solely for such manufacturer.

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

''(6) SIGNIFICANT PROFESSIONAL MEMBERSHIP INTEREST.—The term 'significant professional membership interest' means, with respect to a physician and a covered organization, the physician is a voluntary paying member of such organization or the physician receives professional certification through such organization.''.

SEC. 3. LIMITATION ON TAX DEDUCTIONS FOR ADVERTISING BY CERTAIN MANUFACTURERS OF DRUGS, DEVICES, OR MEDICAL SUPPLIES.

(a) IN GENERAL.—Part IX of subchapter B of chapter 1 of subtitle A of the Internal Revenue Code of 1986 (relating to items not deductible) is amended by adding at the end the following:

''SEC. 280I. LIMITATION ON TAX DEDUCTIONS FOR ADVERTISING BY CERTAIN MANUFACTURERS OF DRUGS, DEVICES, OR MEDICAL SUPPLIES.

''(a) IN GENERAL.—No deduction shall be allowed under this chapter for any taxable year for any expenditure relating to the advertising, promoting, or marketing (in any medium) of any covered drug, device, or medical

supply manufactured by the taxpayer if, during the taxable year, a penalty is imposed on the taxpayer under section 1128G(d) of the Social Security Act (relating to quarterly transparency reports from manufacturers of covered drugs, devices, or medical supplies under Medicare, Medicaid, or SCHIP).

''(b) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

''(1) COVERED DRUG, DEVICE, OR MEDICAL SUPPLY.—The term 'Covered drug, device, or medical supply' has the meaning given such term by section 1128G(g) of the Social Security Act.

''(2) AGGREGATION RULES.—All members of the same controlled group of corporations (within the meaning of section 52(a)) and all persons under common control (within the meaning of section 52(b)) shall be treated as 1 person.''.

(b) CONFORMING AMENDMENT.—The table of sections for such part IX is amended by adding after the item relating to section 280H the following:

''Sec. 280I. Limitation on tax deductions for advertising by certain manufacturers of drugs, devices, or medical supplies.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning ending after the date of the enactment of this Act.

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