**Physician Payment Sunshine Provisions in Healthcare Reform**  
Prepared by AAMC Government Relations  
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Section 6002 of the Patient Protection and Affordable Care Act [P.L. 110-148] amends Title XI of the Social Security Act to insert a new section 1128G to establish a system for reporting payments and other transfers of value to physicians and teaching hospitals from manufacturers of drugs, devices, biological, or medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP), and to require reporting of physician ownership or investment interests in such manufacturers.

**Reporting of Payments or Other Transfers of Value**

On March 31, 2013, and on the 90th day of each following calendar year, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient – defined as a physician or a teaching hospital – or to an entity or individual at the request of or designated on behalf of a covered recipient, shall submit in an electronic form to the Secretary of Health and Human Services the following information for the preceding calendar year:

- The name of the covered recipient.
- The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.
- The amount of the payment or other transfer of value.
- The dates on which the payment or other transfer of value was provided to the covered recipient.
- A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—
  - cash or a cash equivalent;
  - in-kind items or services;
  - stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
  - any other form of payment or other transfer of value (as defined by the Secretary).
- A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—
  - consulting fees;
  - compensation for services other than consulting;
  - honoraria;
  - gift;
  - entertainment;
  - food;
  - travel (including the specified destinations);
  - education;
  - research;
  - charitable contribution;
  - royalty or license;
current or prospective ownership or investment interest;
- direct compensation for serving as faculty or as a speaker for a medical education program;
- any other nature of the payment or other transfer of value (as defined by the Secretary).

- 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.
- Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

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

Physician Ownership

On March 31, 2013, and on the 90th day of each following calendar year, any applicable manufacturer or applicable group purchasing organization shall submit in an electronic form to the Secretary 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) of the Social Security Act) held by a physician (or an immediate family member) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

- The dollar amount invested by each physician holding such an ownership or investment interest.
- The value and terms of each such ownership or investment interest.
- Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described on page 1, except that “physician” shall be substituted for “covered recipient” each place it appears.
- Any other information regarding the ownership or investment interest the Secretary determines appropriate.

Penalties for Noncompliance

Failure to Report: Any applicable manufacturer or applicable group purchasing organization that fails to submit the information required above in a timely manner in accordance with rules or regulations that are promulgated 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.
The total amount of civil money penalties imposed with respect to each annual submission of information by an applicable manufacturer or applicable group purchasing organization shall not exceed $150,000.

**Knowing Failure to Report:** Any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required above in a timely manner in accordance with rules or regulations that are promulgated 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.

The total amount of civil money penalties imposed with respect to each annual submission of information by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.

**Use of Funds:** Funds collected by the Secretary as a result of the imposition of a civil money penalty shall be used to carry out the provisions of this section.

**Procedures for Submission of Information and Public Availability**

Not later than October 1, 2011, the Secretary shall establish procedures for applicable manufacturers and applicable group purchasing organizations to submit information required above to the Secretary; and for the Secretary to make such information submitted available to the public.

The procedures established shall provide for the definition of terms (other than those terms defined in the statute), as appropriate, for purposes of this section.

**Public Availability:** Except as provided below, the procedures established by the Secretary shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted with respect to the preceding calendar year is made available through an Internet website that—

- is searchable and is in a format that is clear and understandable;
- 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), the nature of the payment or other transfer of value, indicated (as appropriate), and the name of the covered drug, device, biological, or medical supply, as applicable;
- contains information that is able to be easily aggregated and downloaded;
- contains a description of any enforcement actions taken to carry out this section, including any penalties imposed, during the preceding year;
- contains background information on industry-physician relationships;
- in the case of information submitted with respect to a payment or other transfer of value pursuant to product development agreements or to clinical investigations (see below), lists such
information separately from the other information submitted and designates such separately listed information as funding for clinical research;

- contains any other information the Secretary determines would be helpful to the average consumer;
- does not contain the National Provider Identifier of the covered recipient; and
- provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

Clarification of Time Period for Review and Corrections: In no case may the 45-day period for review and submission of corrections to information described above prevent such information from being made available to the public in accordance with the dates described above.

Delayed Publication for Payments Made Pursuant to Product Development Agreements or to Clinical Investigations

In the case of information submitted with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established above shall provide that such information is made available to the public on the first date described above, after the earlier of the following:

- The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration; or
- Four calendar years after the date such payment or other transfer of value was made.

Confidentiality: Information pursuant to product development agreements or to clinical investigations shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

Consultation: In establishing the procedures described above, 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 is presented in the appropriate overall context.

Annual Report to Congress
Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

- The information submitted during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (except, in the case of information submitted with respect to a payment or other transfer of value pursuant to product development agreements or to clinical investigations, such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

- A description of any enforcement actions taken to carry out this section, including any penalties imposed, during the preceding year.

**Annual Report to States:**

Not later than September 30, 2013 and on June 30 of each following calendar year, 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 (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

**Relation to State Laws:**

In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient on or after January 1, 2012, the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding such payment or other transfer of value.

The above shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information—

- not of the type required to be disclosed or reported under this legislation;
- excluded by this legislation (see pages 6-7), except in the case of information described in the first bullet under the exclusions listed;
- by any person or entity other than an applicable manufacturer or a covered recipient; or
- to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

**Definitions**
Applicable Group Purchasing Organization: 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 which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

Applicable Manufacturer: A manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

Clinical Investigation: Any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

Covered Device: Any device for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP).

Covered Drug, Device, Biological, or Medical Supply: A drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP).

Covered Recipient: A physician, or a teaching hospital.

Employee: The term “employee” has the meaning given such term in section 1877(h)(2) of the Social Security Act.

Knowingly: The term “knowingly” has the meaning given such term in section 3729(b) of title 31, United States Code.

Manufacturer of a Covered Drug, Device, Biological, or Medical Supply: Any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

Payment or Other Transfer of Value: The term ‘payment or other transfer of value’ means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

EXCLUSIONS – An applicable manufacturer shall not be required to submit information with respect to the following:

- A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same
percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- 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.
- 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.
- 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.
- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- 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)).
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

**Physician:** The term ‘physician’ has the meaning given that term in section 1861(r). It does not include a physician who is an employee of the applicable manufacturer that is required to submit information.