

Transparency Reports and Reporting of Physician Ownership and Investment Interests



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On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, which, among other things, imposes certain reporting obligations on manufacturers of drugs, devices and biologicals; and group purchasing organizations. A new Section 1128G has been added to the Social Security Act, titled, "Transparency Reports and Reporting of Physician Ownership and Investment Interests," which encompasses many aspects of Senator Chuck Grassley's "Physician Payment Sunshine Act" and focuses on greater transparency in relationships between health care professionals and entities and industry.

Payments or Other Transfers of Value

On March 31, 2013, and on the 90th day of each calendar year thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (CR) - which includes physicians (who are not employees of the applicable manufacturer) or teaching hospitals - or to an entity or individual at the request of or designated on behalf of a CR, shall submit to the secretary of Health and Human Services (secretary) specific information with respect to the preceding calendar year. Such required information includes the:

- name and business address of the CR;
- physician specialty and National Provider Identifier (if applicable);
- amount and date of payment or transfer;
- form of payment, some examples include:
 - cash;
 - in-kind items or services; and
 - ownership interests;
- nature of payment or transfer, some examples include:
 - consulting fees;
 - compensation for services other than consulting;
 - gifts;
 - food and entertainment;
 - travel (including the specific destinations);
 - education, research and grants;
 - royalty and license;
 - current or prospective ownership or investment interests.

The new legislation specifically states that 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 CR, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the CR. For example, if an applicable manufacturer enters into a consulting arrangement with a physician and the physician elects not to receive payment directly and requests that payment be made to a charitable organization on his behalf or to his hospital, then the manufacturer would be required to report this payment under the name of the physician (and not the charitable organization or hospital).

Physician Ownership

In addition to the reporting requirements relating to payments or other transfers of value to CRs, on March 31, 2013, and on the 90th day of each calendar year thereafter, applicable manufacturers and applicable group purchasing organizations (GPOs) shall submit to the secretary specific information regarding any ownership or investment interest (other than in a publicly traded security or mutual fund) held by a physician in the applicable manufacturer or applicable GPO during the preceding year. Specifically, applicable manufacturers and GPOs must report information, such as the dollar amount invested by each physician, the value and terms of each such ownership or investment interest, and any payment or other transfer of value provided to a physician holding such an ownership or investment interest (including all of the information specified above for payments and transfers of other value).

Application of New Legislation

All of these new requirements are relevant to applicable manufacturers operating in the United States, who include any entity which is engaged in the production, preparation, propagation, compounding or conversion of any covered drug, biological product, device or medical supply or any entity under common ownership with such entity that provides assistance or support with production, preparation, propagation, compounding, conversion, marketing, promotion, sale or

distribution. Additionally, the physician ownership provision applies to any group purchasing organization operating in the United States that purchases, arranges for or negotiates the purchase of any covered drug, biological product, device or medical supply.

Definition of Payment or Other Transfer of Value

The term "payment or transfer of value" is simply defined as a transfer of anything of value, but the definition contains many exclusions. A few examples of payments or transfers of value that applicable manufacturers are not required to report include:

- a transfer of anything of value that is made indirectly to a CR through a third party in connection with a service where the applicable manufacturer is unaware of the identity of the CR;
- 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 CR by the manufacturer during the calendar year exceeds \$100;
- certain product samples;
- certain educational materials;
- certain loans of devices for evaluation purposes;
- discounts (including rebates);
- in-kind items used for the provision of charity care; and
- a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

Penalties for Noncompliance.

Any applicable manufacturer or GPO that does not timely submit the required information is subject to penalties in the amount of \$1,000-\$10,000 per payment or other transfer of value or ownership or investment interest not reported as required, up to a annual maximum of \$150,000. If the applicable manufacturer or GPO knowingly fails to report as required, then the penalties are increased to \$10,000-\$100,000 per payment or other transfer of value or ownership or investment interest not reported as required, up to an annual maximum of \$1 million.

Public Availability

No later than September 30, 2013, and on June 30 of each calendar year thereafter, the reported information for the preceding calendar year will be made available through a Web site that must be in a searchable format, presented by the topics of information required to be reported, and contain a description of any enforcement actions taken pursuant to this provision. The secretary is charged with establishing procedures no later than October 1, 2011, for submitting the required information to the secretary and for the secretary to make such information available to the public. Applicable manufacturers and GPOs are afforded an opportunity to review and provide corrections to the information submitted for a period of 45 days prior to such information being made available to the public.

Delayed Publication of Confidential Information

If information required to be submitted involves payments or other transfers of value for services furnished in connection with certain research, new applications, development or clinical investigations of a new drug, device, biological or medical supply, then the publication of the information will be delayed to the earlier of the date of 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.

Relation to State Laws

Beginning January 1, 2012, this provision shall preempt any state statute or regulation that requires an applicable manufacturer to disclose or report the type of information required by this federal law. However, this federal law will not preempt additional state requirements, such as, additional information to report, payment or other transfers of value that are excluded under the federal law, application of reporting requirements to those other than applicable manufacturers, or payments or transfers relating to those other than CRs.

If you have any questions about this provision of the Patient Protection and Affordable Care Act, please contact your attorney.

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