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HEALTH CARE REFORM INCLUDES REPORTING REQUIREMENTS REGARDING DRUG AND DEVICE MANUFACTURERS' PAYMENTS TO PHYSICIANS AND TEACHING HOSPITALS

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The Patient Protection and Affordable Care Act (the "PPACA") of 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (the "Reconciliation Act") (collectively referred to as "the Health Care Reform Act") includes a number of new reporting requirements designed to enhance the transparency of certain segments of the health care industry including manufacturers of drugs, medical devices, biologicals and medical supplies. This Alert will focus on the reporting requirements addressing the financial relationships between drug, device, biological and medical supply manufacturers and the physicians and teaching hospitals to which they provide payments or other items of value.

BACKGROUND/GENERAL PROVISIONS

Section 6002 of the Health Care Reform Act sets forth the applicable reporting requirements, penalties and exclusions thereto. Notably, this provision of the Health Care Reform Act was based on the Physician Payment Sunshine Act, a bill originally introduced in 2007 by Senators Herb Kohl (D-WI) and Charles Grassley (R-IA) and re-introduced in 2009 in an attempt to promote transparency regarding conflicts of interest issues that may occur when physicians receive payments or other benefits from drug and medical device manufacturers.

Section 6002 of the Health Care Reform Act adds a new section 1128G to the Social Security Act that requires "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)" to annually submit to the Secretary of Health and Human Services (the "Secretary") certain information regarding the nature of the payment or "transfer of value." An "applicable manufacturer" is defined as any entity operating in the United States or in a territory, possession or commonwealth of the United States "which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological or medical supply" for which payment is available under Medicare or Medicaid and Children's Health Insurance Program ("CHIP") state plans (or a waiver of such plan). A "covered recipient" is narrowly defined as a "physician" or "teaching hospital," however, a physician employee of an applicable manufacturer is not considered a "covered recipient." Further, the term "payment or other transfer of value" is defined to generally mean "a transfer of anything of value."

EFFECTIVE DATE/PROCEDURES

Reporting of payments and other transfers of value that took place during calendar year 2012 must be first reported by March 31, 2013. Beginning thereafter, reports must be made to the Secretary on the 90th day of each subsequent calendar year.

THE REPORTING REQUIREMENTS

Section 6002 requires applicable manufacturers that have made payments or other transfers of value to physicians or teaching hospitals to submit information to the Secretary that includes the following:

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

- if the payment or 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; and
- any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

In addition, reporting is also required in situations where a physician (or an immediate family member of the physician) has an ownership interest (other than through a publicly traded security or a mutual fund) in an applicable manufacturer as described above or a group purchasing organization ("GPO"). Pursuant to Section 6002, beginning on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, the applicable manufacturer or GPO must submit to the Secretary information regarding any ownership or investment interest. The information reported must include the amount invested by each physician, the value and terms of each ownership or investment interest, and any payments or transfers of value made to the physician.

PENALTIES

An applicable manufacturer or GPO that fails to report in a timely manner is subject to civil monetary penalties ranging from $1,000 to $10,000 for each payment or transfer of value not reported, subject to an annual limitation of $150,000. Penalties for "knowing" failures to report are much steeper, ranging from $10,000 to $100,000, with an annual limitation of $1,000,000.

EXCEPTIONS

Section 6002 also lists a number of exceptions to the reporting requirements that include:

- A transfer of anything that is less than $10 in value, unless the aggregate amount transferred during the calendar year exceeds $100 (for years after 2012, these amounts will be indexed for inflation);
- Product samples not intended for sales, but instead 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;
- Items or services provided under a contractual warranty;
- Transfers of value to a covered recipient when he or she is a patient and not acting in a professional capacity;
- Discounts (including rebates);
- In-kind items used in the provision of charity care;
- Dividends and other distributions from publicly traded stocks and mutual funds; and
- A transfer of anything of value to a physician if the transfer is payment solely for the services of the physician with respect to a civil or criminal action or an administrative proceeding.

RULES/PUBLICLY AVAILABLE INFORMATION

Section 6002 requires that, not later than October 1, 2011, the Secretary shall establish procedures for applicable manufacturers and applicable GPOs to submit the required information to the Secretary and procedures for the Secretary to make such information available to the public. By September 30, 2013, and by June 30th of each calendar year thereafter, the Secretary must have the reported information available on an Internet website in a searchable format.

PREEMPTION

The provisions of Section 6002 preempt state laws that require the same types of information to be reported. State laws that are more stringent or that require other types of items to be reported are not preempted.

CONCLUSION

Reporting requirements for drug and device manufacturers included in the Health Care Reform Act were foreshadowed by the Physician Payment Sunshine Act. Drug, device, biological and medical supply companies must become knowledgeable with the requirements of section 6002 of the Health Care Reform Act to prepare to track and document all payments and other items of value provided to physicians and teaching hospitals in 2012 to meet the initial March 13, 2013 reporting deadline. Section 6002's detailed reporting is mandatory and monetary penalties for non-compliance can quickly become very expensive.

For further information regarding Section 6002 of the Health Care Reform Act, please contact Mark Gallant at 215.665.4136 or mgallant@cozen.com, Gregory Fliszar at 215.665.7276 or gfliszar@cozen.com or John Washlick at215.665.2134 or jwashlick@cozen.com.

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