FINAL SUNSHINE RULE REQUIRES REPORTING OF PHYSICIAN OWNERSHIP IN GPOS AND HEALTH PRODUCTS MANUFACTURERS

This article is Part II in a five-part series of articles discussing the recently published federal Physician Payment Sunshine Act ("Sunshine Act"). This article focuses on issues specific to group purchasing organizations and physician investment in health product manufacturers. The first article in the series provided an overview of the major sections of the Sunshine Act and CMS's implementing rule, with a focus on issues of importance to health product manufacturers and entities sharing an ownership structure with manufacturers. The next article, Part III, will discuss the reporting of payments associated with clinical and pre-clinical research, as well as the market research exemption. Part IV will address valuation of payments and transfers of value, as well as general reporting and recordkeeping requirements. Finally, Part V will compare the federal Sunshine Act with similar state requirements in light of federal preemption.

BACKGROUND

On Friday, February 1, 2013, the Centers for Medicare & Medicaid Services ("CMS") unveiled its final rule implementing the Sunshine Act, which was enacted through section 6002 of the Affordable Care Act and creates section 1128G in the Social Security Act. In order to decrease the potential for conflicts of interest in health care, the Sunshine Act requires drug, biological and medical device manufacturers ("Applicable Manufacturers") and group purchasing organizations to annually disclose direct and indirect ownership and investment interests held by physicians and their immediate family members. In addition to reporting ownership interests, the Sunshine Act requires group purchasing organizations to disclose other payments and transfers of value made to physician owners and investors. CMS will post these disclosures to a website that the general public may access.

KEY PROVISIONS

For the definitions of Applicable Manufacturer, Covered Recipients, Teaching Hospital and Covered Products, please see our first article in this series.

Group Purchasing Organizations. Section 403.902 of CMS's final rule defines an Applicable Group Purchasing Organization ("GPO") as any entity that (1) operates in the United States, or a territory or commonwealth of the United States; and (2) "purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply ("Covered Products") for a group of individuals or entities, and not solely for use by the entity itself." In the final rule, CMS clarified that a GPO operating in the United States is one that (1) has a physical location within the United States or in a territory, possession or commonwealth of the United States; or (2) otherwise conducts activities within the United States or in a territory, possession or commonwealth of the United States, either directly or through a legally authorized agent.

CMS declined to expand the definition of GPO to include entities that purchase Covered Products in bulk only for use by commonly-owned entities, such as when a hospital system purchases in bulk for its "own use" and not for resale to other unrelated entities. CMS also clarified that the definition does not include "rare and circumstantial resale" of products in response to drug shortages.

Physician-Owned Distributors. Both Congress and CMS specifically intended to include Physician-Owned Distributors ("PODs") among those GPOs subject to the ownership and investment reporting requirements. Although CMS explained that the rule is written to include most entities that purchase Covered Products for resale to others, the language of the statute does not encompass all POD models. For example, CMS declined to limit the exclusion for entities that purchase products for their own use to only those entities that are the end users of the device based on billing under the same provider or supplier number as the entities that purchased the product. Additionally, because the Sunshine Act defines a GPO as an organization purchasing for a group, a POD with only a single buyer is not required to comply with ownership and investment reporting as it is not a group purchaser.

Depending upon its structure, a POD may also qualify as an Applicable Manufacturer and be required to report payments or other transfers of value to Covered Recipients as described in our first article in this series. For example, many PODs take title to the products they distribute, and title-holding distributors are subject to the same reporting requirements as Applicable Manufacturers. PODs should also be

aware of the common-ownership rule: entities that provide necessary and integral "assistance and support," such as marketing and distribution activities, to an Applicable Manufacturer with which a common ownership structure is shared, are subject to full reporting requirements.

Covered Recipients: Teaching Hospitals, Physicians and Their Immediate Family Members. GPOs and Applicable Manufacturers must annually disclose direct and indirect ownership and investment interests held by physicians and their immediate family members. They are not required to report any ownership or investment interests held by teaching hospitals. There is no exclusion from reporting for bona fide employees, so GPOs and Applicable Manufacturers must report investment and ownership interests held by their employees who are physicians or physicians' immediate family members.

The final rule defines a physician's "immediate family members" in a manner similar to the Stark law regulations, specifically including a physician's spouse, parents, children, siblings, step-parents, step-siblings, in-laws, grandparents, spouses of grandparents and grandchildren, regardless of whether the person is a natural or an adopted family member. It may be difficult for GPOs and Applicable Manufacturers to identify immediate family members because physicians are not required to disclose their relations. For this reason, there is an exception from reporting when the Applicable Manufacturer or GPO does not know that a physician's immediate family member holds a reportable ownership or investment interest. Similar to the False Claims Act knowledge standard, the Sunshine Act's definition of ''know'' provides that a person, with respect to information, has actual knowledge of the information, acts in deliberate ignorance of the information or acts in reckless disregard of the truth or falsity of the information.

Ownership and Investment Interests. The definition of ownership or investment interests in the final rule is similar to the Stark law definition. It includes, but is not limited to:

- Stock and stock options (equity);
- Partnership shares;
- Limited liability company memberships or units; and
- Loans, bonds or other financial instruments that are secured with all or a portion of an entity's property or revenue.

The final rule also includes exceptions from the definition of ownership or investment interest similar to those of the Stark law, including:

- An interest held in an employer-based retirement plan;
- Unsecured loans subordinated to a credit facility;
- Stock options or convertible securities received as compensation, until converted to equity; and
- Publicly traded securities and mutual funds as described in section 1877(c) of the Social Security Act.

It may be difficult to differentiate payments or transfers of value to a physician from a physician's ownership or investment interest. For example, some stock options will be considered ownership or investment interest, whereas other stock options could be considered payments or transfers of value. In some situations, stock options might not need to be reported until exercised.

Payments and Transfers of Value. A GPO is not required to report payments or transfers of value to a Covered Recipient when the Covered Recipient does not also hold ownership or investment interests in the GPO. However, when a physician is a holder of ownership or investment interests in the GPO, the GPO must report both the physician's ownership/investment interests and any other payments and transfers of value made to that physician. Indirect payments or transfers of value made by a GPO to the physician through a third party, including the physician's family member or a trust, must also be reported if the GPO requires, instructs, directs or otherwise causes the third party to provide the payment or transfer of value to the physician. The GPO need not report indirect payments of which it is unaware, so long as it has satisfied the "knowledge standard" with a reasonable inquiry.

THE REPORTING PROCESS

Registration. All Applicable Manufacturers and GPOs that have reportable ownership or investment interests must register with CMS within 90 days of the end of the calendar year for which a report is required. Reporting entities must register individually, regardless of whether they intend to be part of a consolidated report being submitted by another entity. Applicable Manufacturers and GPOs that do not have

reportable ownership or investment interests held by a physician or physician's immediate family member during the previous calendar year are not required to register or report.

Timing. Applicable Manufacturers and GPOs must submit reports for each calendar year by the following March 31 or 90th day of the subsequent calendar year. Only ownership or investment interests held on or after August 1, 2013 must be reported to CMS for the calendar year 2013 report that is due to CMS by March 31, 2014.

Report Details. Reports of physician ownership and investment interests must include the following identifying information about the physician:

1. Name as listed in the National Plan & Provider Enumeration System ("NPPES"), indicating whether the interest is held by the physician or an immediate family member;
2. Primary business address;
3. Medical specialty;
4. National Provider Identifier (if applicable and as listed in NPPES); and
5. State professional license number.

Information about the financial interest to be reported includes:

1. Dollar amount invested by the physician or the immediate family member;
2. Value and terms of each ownership or investment interest; and
3. Any other payments or transfers of value provided to the physician holding an ownership or investment interest, either directly or indirectly through a third party.

CMS does not require that an immediate family member's name or relationship to the physician be reported. Therefore, Applicable Manufacturers and GPOs may report ownership and investment interest in aggregate across multiple family members, instead of reporting at the individual person level, so long as the multiple family members have ownership or investment interests with the same terms.

When an Applicable Manufacturer has ownership and investment interests to report for Covered Recipients, it should report them using the template for payments or other transfers of value and describe them as standing ownership or investment interests. When an Applicable Manufacturer has ownership and investment interests to report for a physician who is not a Covered Recipient, the Applicable Manufacturer should report using the ownership or investment interests template. Comparatively, GPOs should not file two separate reports. When a GPO also has payments or other transfers of value to report, it should simply add this information to the report detailing physician ownership and investment interests.

Templates and reporting FAQs are now available on the newly launched CMS OPEN PAYMENTS website.

IMPACT

CMS estimates that approximately 1,150 Applicable Manufacturers and 420 GPOs will be subject to reporting requirements. CMS estimates that reporting compliance will cost each Applicable Manufacturer and GPO an average of $102,461 annually. CMS also estimated that GPOs will need to dedicate 728 hours to ensure reporting compliance in the first year and 546 hours in each year thereafter.

PRACTICAL TAKEAWAYS

GPOs and Applicable Manufacturers. GPOs and Applicable Manufacturers should make reasonable inquiries to identify physicians and immediate family members of physicians that hold ownership or other investment interests in their companies. GPOs and Applicable Manufacturers should identify any payments or other transfers of value made to physician owners/investors that are not related to ownership or other investment interests but which must be additionally reported as a payment or transfer of interest to a Covered Recipient. Applicable Manufacturers and GPOs should also develop communication mechanisms with physicians so that parties may come to agreement on data before it is disclosed to CMS.

GPOs and PODs. In addition to identifying and reporting ownership and investment interests held by physicians and their immediate family members, both GPOs and PODs should (1) identify any situations where they make or hold title to any products that meet the definition of Covered Products; and (2) identify any financial relationships with Covered Recipients, especially as related to those Covered Products. GPOs and PODs should also identify any Applicable Manufacturers with which they share common-ownership and to which they provide marketing or distribution support. PODs in particular may benefit from reevaluating their corporate structures and related marketing, supply chain, clinical and other contracting agreements to eliminate or minimize exposure to reporting requirements.

Physicians and Hospitals. Physicians and hospitals whose relationships may qualify for reporting as either Covered Recipients or as physician owners/investors should register with CMS to receive notifications of new data. As a good risk management practice, a hospital may benefit from monitoring its physicians' financial relationships through the CMS website as such information has potential public relations and compliance implications. In the context of GPOs, hospitals and physicians should watch out for GPO fees being incorrectly reported by Applicable Manufacturers or GPOs as payments or transfers of value. A hospital or physician may also wish to consider its vendors based on their reporting requirements. For example, a GPO generally is not required to report payments and transfers of value to non-owner/investor physicians, whereas a POD may be required to do so because of its ownership structure.

If you have questions about the Sunshine Act or GPOs, or would like help designing a Sunshine Act compliance strategy, please contact:

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