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CMS PUBLISHES THE FINAL PHYSICIAN PAYMENT SUNSHINE RULE

This article is Part I in a five-part series discussing the federal Physician Payment Sunshine Act. This first installment provides 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. Part II will address issues specific to Group Purchasing Organizations and physician investment in health product manufacturers. 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.

EXECUTIVE SUMMARY

On Friday, February 1, 2013, the Centers for Medicare and Medicaid Services ("CMS") unveiled the final rule implementing the Physician Payment Sunshine Act ("Sunshine 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") to annually disclose payments they make to physicians and teaching hospitals ("Covered Recipients") when related to certain products ("Covered Products"). It also requires Applicable Manufacturers and Group Purchasing Organizations ("GPOs") to disclose certain ownership and investment interests held by Covered Recipients and their immediate family members. CMS will post these disclosures to a website that the general public may access.

CMS's final rule provides additional clarification on who must report, what must be reported, mechanisms for reporting and editing data, payment classification and dispute resolution. The final rule can be found here.

KEY PROVISIONS OF THE FINAL RULE

Covered Products. These include any drug, device, biological or medical supply for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under a hospital inpatient or outpatient prospective payment system) and is: (1) a drug or biological that requires a prescription to be dispensed; or (2) a device that requires premarket approval or premarket notification from the Food and Drug Administration ("FDA").

Covered Recipients. These include teaching hospitals, as well as doctors of medicine and osteopathy, dentists, podiatrists, optometrists and chiropractors, but not physician-residents or bona fide employees of manufacturers. A teaching hospital is any hospital that receives Medicare payments for indirect medical education, direct graduate medical education or psychiatric hospital indirect medical education.

Applicable Manufacturers. The entity holding FDA approval, clearance or licensure for a Covered Product is typically an Applicable Manufacturer, but several nuances and exceptions exist, including:

- Hospitals and hospital pharmacies that manufacture products for use only by the hospital's own patients are not Applicable Manufacturers; and
- A distributor, wholesaler, repackager or relabeler that takes title to a Covered Product is an Applicable Manufacturer.

Generally, an Applicable Manufacturer that makes both Covered Products and other products must report all payments or transfers of value to Covered Recipients, even if those payments are not associated with a Covered Product. However, exceptions include:

- A contract manufacturer that is not involved in a Covered Product's marketing and does not hold the product's FDA license, approval or clearance must report only payments related to the Covered Product, rather than all products; and
- Applicable Manufacturers with less than ten percent of annual gross revenues coming from Covered Products must report only payments or other transfers of value related to Covered Products, rather than all products.

Commonly-Owned Entities. There are special reporting rules for entities under common ownership with an Applicable Manufacturer, which

can include parent companies/subsidiaries, separate divisions of a corporate entity and circumstances where the same individuals or entities own five percent or more of total ownership in two or more entities. Even if a commonly-owned entity does not manufacture any Covered Products, it must still comply with Sunshine Act requirements if it provides the Applicable Manufacturer with assistance and support necessary or integral to the production, marketing, promotion, sale or distribution of a Covered Product (this would not include human resources functions). However, it need only report payments or transfers of value to Covered Recipients that relate to Covered Products.

Payments and Transfers of Value. Payments or other transfers of value to Covered Recipients that must be reported by Applicable Manufacturers and commonly-owned entities include: consulting fees, honoraria, gifts, travel, entertainment, research, charitable contributions, royalties or licenses, grants and food. Items excluded from reporting include:

- Anything valued at less than $10, so long as the aggregate amount transferred to that Covered Recipient does not exceed $100 annually;
- Product samples and educational materials intended for patient use or benefit;
- The loan of a device for a trial period not to exceed 90 days in one year for the purpose of evaluating the device, including disposable or single-use devices and medical supplies intended to last for no more than 90 days;
- Items or services provided according to contractual agreement, including warranty, maintenance and recall provisions, even if the contract has expired;
- Discounts, including rebates;
- Payments when the Applicable Manufacturer does not know the identity of the Covered Recipient, such as when a payment is made through a third party to conduct a double-blinded market research study; and
- Compensation for speaking at a continuing education program, if the program meets certain accreditation standards, the Applicable Manufacturer does not select or pre-identify the Covered Recipient speaker and the Applicable Manufacturer does not directly pay the Covered Recipient speaker.

Clinical and Pre-Clinical Research. Research payments or other transfers of value made under a product research or development agreement may be delayed from publication on CMS's website when made in connection with research on or development of a new drug, device, biological or medical supply, a new application of an existing product or clinical investigations regarding a new product.

Physician Ownership Interests. Applicable Manufacturers and GPOs must report certain ownership or investment interests held by physicians or their immediate family members. Required disclosures include: stock, excluding interests held in a publicly traded security or mutual fund; stock options, other than those received as compensation until exercised; partnership shares or limited liability company memberships; and loans or other financial instruments secured by a portion of the entity's property or revenue. The law does not require manufacturers or GPOs to report ownership or investment interests held by teaching hospitals.

Reporting Dates. The final rule delayed the initial collection and reporting of data. Applicable Manufacturers and GPOs now have until August 1, 2013, to begin collecting data and until March 31, 2014, to file their first reports (for the period August through December of 2013). CMS will release this data on a public website by September 30, 2014. In subsequent calendar years, reports must be filed by the 90th day of the calendar year and include all data from the previous calendar year. CMS is still developing an electronic system to facilitate the reporting process and also intends to publish Frequently Asked Questions for using the online data.

Resolving Disputes and Correcting Errors. Applicable Manufacturers will have 45 days to review and correct data prior to CMS making it public. Covered Recipients may subscribe to a CMS list-serve to be notified of information pertaining to them and will then have at least 15 days to dispute information. Disputes must be resolved directly between the Covered Recipient and the Applicable Manufacturer or GPO. If the dispute is not resolved, CMS will publish the original data and mark it as disputed.

Record Keeping. Applicable Manufacturers and GPOs must maintain all books, contracts, records, documents and other evidence for a period of at least five years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the website. Although physicians and teaching hospitals are not required to maintain their own records, failure to do so may inhibit their

ability to dispute information from Applicable Manufacturers and GPOs.

Penalties and Compliance Risks. Violators can be subject to civil monetary penalties of up to $150,000 annually for failure to report and up to $1 million annually for knowingly failing to report. CMS and the Department of Health and Human Services Office of the Inspector General may audit, inspect and evaluate any evidence held by Applicable Manufacturers and GPOs to analyze their compliance with reporting requirements. CMS and HHS acknowledge that they may use these records and public data to prosecute investigations under the False Claims Act, Anti-Kickback Law and the Stark Law.

Federal Preemption of State Laws. The Sunshine Act preempts State and local laws that require reporting of any payments or transfers of value from an Applicable Manufacturer or GPO to a Covered Recipient that are required under the Federal law. State and local agencies may require reporting of non-required categories of payments or transfers of value, including payment categories excluded by the Federal law, with the exception of those that do not meet the minimum dollar threshold of $10 per item/$100 aggregate annually for each Covered Recipient. In addition, States and localities may impose total gift bans and may require reporting of payments or other transfers of value not required to be reported at all under the Federal law, including payments to non-covered recipients or by non-applicable manufacturers.

PRACTICAL TAKEAWAYS

Manufacturers. Manufacturers should evaluate whether they must comply with the law by (1) determining if they make or hold title to any products that meet the definition of Covered Products, and (2) identifying any financial relationships with Covered Recipients, especially as related to those Covered Products. Information about relevant interactions with Covered Recipients must then be tracked at both individual and aggregate levels and be in a format that facilitates annual reporting. Applicable Manufacturers may wish to reevaluate their marketing, supply chain, clinical and other contracting structures to eliminate or minimize exposure to reporting requirements. Lastly, Applicable Manufacturers should develop communication mechanisms with Covered Recipients so that they may come to agreement on data before it is disclosed to CMS.

Commonly-Owned Entities. Any entity that shares a corporate structure or joint venture with another entity that manufactures or refurbishes medical products, takes title to such products or is registered with the FDA as the product's manufacturer should (1) determine whether the manufacturing entity is an Applicable Manufacturer, (2) classify the nature of support given to the Applicable Manufacturer - critical or non-critical, and (3) identify any payments made to Covered Recipients. Commonly-owned entities may wish to reorganize corporate structures or discontinue certain types of support to Applicable Manufacturers in order to avoid reporting requirements.

Health Care Providers. Even though the Sunshine Act imposes no reporting obligations on health care providers, the transparency it engenders may expose providers and hospitals to heightened legal risk under anti-fraud and abuse laws (the False Claims Act, the Stark Law and the Anti-Kickback Law); federal regulations on conflicts in clinical research; and patient injury lawsuits involving the safety of medical devices or drugs. This transparency may also fuel increased media and patient scrutiny of perceived conflicts and drive changes to the conduct of clinical research and supply chain contracting. Physicians and teaching hospitals that may be Covered Recipients should establish internal procedures to track their own information and regularly review CMS's publicly reported data. Affected health care providers should also ensure that their compliance policies and procedures adequately identify non-permissible conflicts of interest and describe strategies to manage other conflicts.

If you have questions or would like help designing a Sunshine Act compliance strategy, please contact Mark Dahlby at 414-721-0902 or mdahlby@hallrender.com, Susan Bizzell at 317-977-1453 or sbizzell@hallrender.com or your regular Hall Render attorney.