Physician Payment Sunshine Act Reports Delayed by CMS; Proposed Rule Includes Physician Owned Distributorships

By Thomas William Mayo | January 3, 2012

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The Centers for Medicare and Medicaid Services (CMS) has delayed the start date for data collection of payments made to physicians and teaching hospitals by drug and device manufacturers and group purchasing organizations (GPOs). Under the Physician Payment Sunshine Act (the "Sunshine Act"), such payments were to have been recorded beginning on January 1, 2012. However, because CMS was late in publishing proposed implementation rules, payments to physicians and teaching hospitals by drug and device manufacturers and GPOs will not be recorded until CMS publishes final rules sometime in 2012. In another important development, CMS also proposed that physician owned distributorships (PODs) be included in the reporting requirements under the Sunshine Act. Even though the reporting requirements have been delayed, all drug and device manufacturers, GPOs and PODs that make any kind of payment or remuneration to physicians in any amount should begin implementation efforts now. The reporting requirements of the Sunshine Act will cover an estimated 1,150 drug and device manufacturers, 420 GPOs, 669,000 physicians and 1,100 teaching hospitals. Failure to comply with the Sunshine Act carries penalties ranging up to $1 million annually.

The Sunshine Act was included in the 2010 Patient Protection and Affordable Care Act after the Medical Payments Advisory Commission (MedPAC) found that some drug and device manufacturer interactions with physicians were associated with the rapid prescribing of new and more expensive drugs as well as MedPAC's concern that manufacturers' influence over physician education may skew the information physicians receive. As a result, MedPAC recommended that financial relationships between drug and device manufacturers and physicians and teaching hospitals be made transparent.

What Must Be Reported

The Sunshine Act requires that manufacturers of drugs, biologicals, devices and medical supplies, as well as GPOs, report all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals and travel) made to physicians and teaching hospitals in excess of $10, with a minimum annual threshold of $100 to each physician and teaching hospital. Additionally, manufacturers and GPOs must report ownership or investment interests held in those entities by physicians or their immediate family members. The Act contained a start date of January 1, 2012; however because CMS did not meet a statutory deadline of October 1, 2011 for providing implementing regulations, the starting date for collecting this data has been postponed until CMS publishes final regulations sometime in 2012.

Once CMS receives reports concerning payments to and investments by physicians and teaching hospitals, it will publish the data on a publicly available website. The information on the website will be aggregated, downloadable and searchable, pursuant to requirements contained in the Sunshine

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Act. The public will then be able to see what financial relationships exist between GPOs, PODs, drug and device manufacturers and physicians and teaching hospitals.

In its draft regulations, CMS proposes to define applicable manufacturers and GPOs as entities that manufacture, purchase or arrange for the purchase of any drug, device, biological, or medical supply for sale or distribution in the United States that is available for payment by Medicare, Medicaid or the Children's Health Insurance Program (CHIP), and for which a prescription is required. CMS also proposes to include PODs in its definition of GPOs subject to the reporting requirements.

Applicable manufacturers and GPOs will have to report all transfers of value to physicians, their immediate family members and teaching hospitals. Certain investment and ownership interests by physicians and their immediate family members in such entities will also have to be disclosed. CMS proposes to identify covered physicians by their NPI numbers and will publish a list of teaching hospitals by listing those that receive any Medicare indirect or direct graduate medical education (IME or GME) payments. Manufacturers and GPOs will have to consult with these lists to determine if the recipient of any payments or transfer of value is a "covered recipient" under the Sunshine Act.

A Complicated Reporting Structure

The proposed regulations contain a complicated set of procedures that manufacturers and GPOs must follow in order to identify and report the nature and type of payments, including indirect payments, made to "covered recipients." For example, manufacturers will have to report the drug, device, biological or medical supply that is "associated" with each payment, and will have to classify each payment according to a 13-part category list. If a payment is associated with multiple categories (e.g., if a physician received meals and travel associated with a consulting fee), the manufacturer will have to itemize each segment of payment and report it separately. Furthermore, if a payment is made to a physician group, manufacturers will have to identify which physician is the principal investigator who will be reported to have received the payment.

Manufacturers and GPOs will have to build robust reporting systems in order to capture the detailed information required under the Sunshine Act, especially since any payment or transfer of value over $10 to a covered recipient must be reported. For example, if a manufacturer's sales representative brings $25 worth of bagels and coffee to a *solo* physician's office for a morning meeting, this must be reported since the per covered recipient cost is $25 and falls above the $10 threshold. However, if the practice group includes *five* physicians, the per-covered recipient cost is only $5, so the payment in that instance need *not* be reported. There will certainly be confusion and anxiety as entities struggle with these reporting requirements, while potentially facing civil monetary penalties of up to $1 million if they do not report correctly.

Research Payments

The Sunshine Act provides for a delayed publication of payments or other transfers of value from manufacturers to physicians and teaching hospitals made pursuant to product research or development agreements or clinical investigations. The delay in publication (but *not* reporting) is designed to maintain confidentiality for proprietary information related to the development of new drugs, devices, biologicals and medical supplies. Publication will be delayed until the earlier of FDA approval, licensure or clearance or 4 calendar years after the date of payment. A delay in publication will only be granted for bona fide research that is conducted pursuant to a written statement or contract between the parties in which there is a written research protocol. CMS

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proposes further regulations detailing exactly how delays will be granted for differing types of research development.

Opportunity to Review and Correct Information Prior to Publication

Covered recipients will have the opportunity to review and correct information related to them for 45 days prior to the data being made available to the public. After reports have been submitted to CMS, it will aggregate the data by individual covered recipient and physician owner or investor across applicable manufacturers and GPOs. Once the aggregation is complete, CMS will notify all affected parties about the procedures for review, and 45 days will be allowed for parties to review and correct data. CMS has stated it will not get involved in any dispute between covered recipients and manufacturers and GPOs concerning the receipt, classification or amount of payment or other transfer of value, or ownership or investment interest. Instead, CMS urges the parties to resolve the disputes amongst themselves. If a matter cannot be resolved, the data will still be published, but will be marked as disputed.

For more information concerning the proposed Physician Payment Sunshine Act reporting requirements, please contact one of the following Haynes Boone attorneys.

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[1] The Physician Payment Sunshine Act is located in Section 6002 of PPACA and has been added to Section 1128G of the Social Security Act.

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