Research

Physician Payment Sunshine Act: A Primer

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INTRODUCTION

This month, the Centers for Medicare and Medicaid Services (CMS) will release data on the financial relationships between physicians and health care industry manufacturers for the first time. This data will be published under what is known as the "Sunshine Act," and will allow public access to the financial interactions between doctors, drug manufacturers, device manufacturers, teaching hospitals, and other entities. The Act aims to better inform patients of financial relationships regarding the promotion and sale of new medical devices and prescription drugs. In preparation for the release of this data, drug and device manufacturers have reported information on physician and hospital payments to CMS and physicians had the opportunity to review information regarding their practice or facility.

As an important piece of the innovation process, physicians and manufacturers use these financial arrangements to work together to promote new products and educate providers about new options for patient care. Since this financial interaction is a critical piece of furthering medical innovation, many stakeholders want to ensure that payments received by physicians and hospitals are viewed in the proper light – not as coercive tactics that could harm patients. This primer outlines the particulars of the Sunshine Act, those impacted by its requirements, and possible challenges in adhering to its guidelines.

BACKGROUND

The Physician Payments Sunshine Act was originally introduced in 2007 by U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI),[1] and was enacted as part of the Affordable Care Act (ACA) passed in March of 2010. The Sunshine Act seeks to provide greater transparency to the long-standing practice for drug and device manufacturers and group

purchasing organizations (GPOs) to compensate physicians for participating in product development, educational events, and promotional efforts. Physicians are typically sought after to educate patients and other physicians on recent innovations because of their expertise and unique perspective in the health care field.[2] In exchange for their participation, physicians receive payments from manufacturers in the form of speaking fees, consulting fees, research funds, or other methods of compensation.

HOW IT WORKS

The ACA requires certain "applicable manufacturers" and GPOs to report multiple forms of payments to "covered recipients." In the form of an annual report, GPOs and manufacturers submit required payment information to CMS. CMS publishes the information in a database available to the public each year. These reports are a way to elucidate how these dollars are spent, requiring manufacturers and GPOs to disclose payments and ownership or investment interests received by physicians as forms of payment. The information reported depends on the type of group submitting the information; reporting requirements are different for manufacturers and for GPOs.

IMPACTS ON INTERESTED PARTIES

This law impacts three groups: manufacturers of "covered products," GPOs, and "covered recipients." "Covered products" that are subject to reporting requirements include drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program.[3] "Covered recipients" include health care providers (usually physicians) and teaching hospitals – CMS estimates that the first year of Sunshine Act reporting will impact 224,000 physicians.[4]

Applicable Manufacturers

An applicable manufacturer includes any entity that is engaged in production, preparation, propagation, compounding, or conversion of a "covered product." An entity can also be included in reporting requirements if it is owned by the applicable manufacturer and provides services to support a covered product. Manufacturers have to report any payments to physicians or teaching hospitals as well as any ownership or investment interests held by physicians or physicians' immediate family members.[5]

Group Purchasing Organizations

GPOs, on the other hand, are entities that make purchases on behalf of several

organizations, such as nursing homes or hospitals, utilizing the large volume in order to leverage a significant discount.[6] GPOs only have to report physician payments and investments, but are not required to report information from teaching hospitals.[7]

REPORTING REQUIREMENTS

Regulation clearly defines the types of payments that must be reported as four forms of payment: ownership in stock or stock options, in-kind items or services, cash or cash equivalents, and returns on investments.[8] Further, when manufacturers and GPOs are reporting all of this information, it must be filed into a mutually exclusive category of one of sixteen options:[9]



Each year, the summarized information is to be distributed to Congress, states, and the public. The yearly transparency report includes aggregate information from each applicable manufacturer and GPO, as well as any penalties levied. Along with the annual report, the statute requires the Secretary of Health and Human Services to publish the reported data online in a format that is "downloadable, easily searchable, and aggregated."[10] The report is useful to outside parties for a variety of reasons. For example, groups awarding grants can recognize physician conflict of interest prior to beginning research, and patients can seek a second opinion if suggested treatments happen to coincide with the financial relationships of the physician.

Some exceptions to reporting exist for manufacturers that do not provide large sums of payments. Any manufacturer that did not grant payments to practices or teaching hospitals, or provide physician ownership or investment interests is not required to submit a transparency report. For those manufacturers that do provide payments, all transfers under $10 do not need to be reported unless the entity has a cumulative transfer of $100 or more. Product samples intended for patient use, continuing medical education, patient education materials, short-term loans returned in less than 90 days to evaluate equipment, discounts, and rebates are not to be included in the annual transparency reports.[11]

Timeline

The first reporting time frame is shorter, covering August 2013 to December 31, 2013. In phase one of reporting, manufacturers and GPOs submitted information to CMS from February 18, 2014 to March 31 2014. In phase two, manufactures and GPOs reviewed their

submitted data between June 1, 2014 and June 30, 2014. Physicians then review the payment data from July 14, 2014 until September 11, 2014.[12] The database will be available on September 30, 2014 with some limitations. For 2014, about one third of the Sunshine Act data will be withheld from the Open Payments database; specifically it will not include research grants from drug manufacturers to physicians that were received through an intermediary.[13] In the future, manufacturers will register with CMS each year within 90 days of the end of the calendar year. Following registration, a completed transparency report must be submitted by the 90th day of each calendar year.

Penalties

GPOs and manufacturers that fail to submit a report by the 90th day of each calendar year could be subject to a minimum charge of $1,000 per payment or up to $10,000 for each payment. Annually, the maximum penalty is $150,000 for failure to report. For a knowing failure to submit required information, the penalties become more severe. Applicable manufacturers and GPOs that knowingly do not submit reporting information are subject to a fee of $10,000 to $100,000 per payment not reported. The annual limitation on knowing failure to report is $1,000,000. The amount of the penalty is determined based on the length of time the applicable manufacturer or GPO knew of the payment, the amount of the payment, the level to which the GPO or manufacturer can be held legally responsible for the payment reporting error, the amount and nature of information reported in error, and the degree of diligence implemented to correct the missed reporting.[14]

BUDGETARY IMPACT

The CMS final rule estimated the Sunshine Act would cost approximately $269 million in compliance cost the first year and $180 million in year two. This cost will largely fall on large manufacturers and GPOs who have the most interactions to report; an estimated one to ten full time employees per manufacturer will be necessary to comply with the reporting requirements.[15] However, 75 percent of manufacturers and GPOs are considered small with few (if any) payments, transfers of value, ownership, or investment interests to report.[16] For these smaller manufacturers, one full time administrative employee and a small fraction of a compliance officer's time will be necessary for following the reporting requirements in the first year.[17] The CMS final rule calculated the average burden for the first year at $80,000 for small manufacturers.

In total, approximately 1,150 manufacturers and 420 GPOs are expected to submit reports. Full time employees committed to reporting requirements will coordinate data collection and submission, build and maintain reporting systems, train staff, research physician

information, review aggregated data sent to CMS, and respond to any challenges from physicians on the reported information.[18] More than 224,000 physicians are anticipated to review the yearly report, and a portion will need to submit changes. The expected review time per physician is six hours in year one, in which they will review the report and submit any errors found. Approximately 1,100 teaching hospitals will go through the same process and are estimated to require 120 staff hours each.[19]

IMPLEMENTATION CHALLENGES

For Physicians

Many stakeholders have supported the goal to promote transparency; however, there are concerns regarding the additional regulatory burden on physicians, the potential for misrepresentation of information in public reports, and possible diminished innovation resulting from more limited physician-manufacturer relationships. The American Medical Association (AMA) advocates specifically for measures in the policy that do not add to a physician's paperwork burdens.[20] Currently, there are no additional regulations for physicians and teaching hospital participation other than a recommended review of the manufacturer's submitted information. Physicians will only submit paperwork if they would like to challenge an inaccurate or misleading report.[21]

In recent months, more than 100 physician groups composed a letter to CMS regarding the short length of time available for physicians to review the information on financial contributions they received. The letter argues that problems with the website used to review financial data are causing a delay in physicians' abilities to properly assess the information, and requests a delay of publication until March 31 of 2015.[22] Following outcry from physician groups, CMS extended the timeframe for physician review of manufacturer and GPO reports before the information is released to the public. The original time period for physician review was from July 14 to August 27, and CMS has extended the review period through September 11. However, CMS declined the request to delay the Open Payments website, stating that the database will go live on September 30 as scheduled.

For Manufacturers

Stakeholders have called for clear definitions and guidelines combined with consistent industry information sharing to avoid inaccurate reports from being released to the public. During initial discussions of transparency legislation, AdvaMed – the trade association for medical technology and device manufacturers – requested the inclusion of contextual information in the database.[23] AdvaMed argues that, without the inclusion of this type of

information, all physician-manufacturer relationships could be construed as inappropriate or a disincentive for physicians to participate in the development of new technologies and pharmaceuticals. Major industry groups have urged CMS to disclose information on the context that will be given along with the dollar amounts awarded to physicians. However, CMS has not allowed these industry groups to review the data or contextual information included in the database. CMS has stated that the agency plans to include the nature of each payment or transfer of value, and will make payment context available.[24]

CONCLUSION

The Physician Payments Sunshine Act has the potential to give patients greater information when making health care decisions and could deter the influence of clinical decisions based on financial relationships between physicians and manufacturers. The success of the Sunshine Act will be significantly impacted by the ability of CMS to collect and organize data, settle disputes between physicians and manufacturers, and publicize the data in a timely manner. As the implementation continues many stakeholders are encouraging CMS to provide context to the data in order for patients and interested parties to fully understand these financial interactions.

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[1] Physician Payment Sunshine Act of 2007, S. 2029