

The Physician Payment Sunshine Act – Answers to the 5 W's

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Introduction

The Physician Payment Sunshine Act was enacted as part of the sweeping federal health reform legislation Accountable Care Act. The Centers for Medicare and Medicaid Services recently released final rules that implement the Sunshine Act. In general, the Sunshine Act requires two things. First, applicable manufacturers of drugs, medical devices, biologicals or medical supplies must track and report payments made to physicians. Second, applicable manufacturers and group purchasing organizations must disclose for public reporting any ownership or investment interests held by physicians.

Physicians should be aware of the ins and outs of the Sunshine Act to avoid any unintended and/or uncomfortable public reporting and disclosures. Answering the proverbial “5 W” questions regarding the Sunshine Act is an important first step in guarding against any of these unintended risks.

Who is Required to Report?

The Sunshine Act requires public reporting and disclosure from manufacturers of drugs, medical devices, biologicals and medical supplies and group purchasing organizations. A manufacturer is any entity operating in the United States that produces or prepares at least one drug device, biological or medical supply covered under Medicare, Medicaid or the Children's Health Insurance Program. Manufacturers operate in the United States if they have a physical location or conduct activities in the United States. Distributors and wholesalers are also manufacturers for purposes of the Sunshine Act if these entities hold title to the drug, device, biological or supply.

What Must be Reported?

The Sunshine Act requires reporting and disclosure of two items: (1) payments and other transfers of value to physicians; and (2) certain ownership or investment interests held by physicians. For any payments or transfers of value, both the “form” and the “nature” of the payments or transfers must be reported. Examples of the “form” include cash or cash equivalents, in-kind items or services, stock, stock options, or any other ownership interest, dividend, profit, or other return. Description such as consulting fees, honoraria, entertainment, food, and travel, royalties, or

grants speak to the “nature” of the payments or transfers.

The Sunshine Act does exclude certain payments. For example, payments of less than \$100 in the aggregate during any given year, providing educational materials that directly benefit patients and intended for patient use, discounts and rebates, and product samples are not subject to reporting under the Sunshine Act.

The Sunshine Act defines ownership or investment interests in a fairly straightforward manner. An ownership or investment interest can be direct, indirect, and through debt, equity, or other means. This includes stock, stock options, partnership shares, limited liability company membership units, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue. That said, ownership or investment interests in a publicly traded security or mutual fund are excluded under the Sunshine Act.

When Are Reports Due?

There are various key dates to keep in mind with respect to the Sunshine Act. Beginning August 1 and continuing through December 31, 2013, manufacturers subject to the Sunshine Act must begin to collect and track payment, transfer, ownership, and investment information. Beginning January 1, 2014, the collection and tracking of this information will be on a calendar year basis. All reports for the partial year 2013 are due by March 31, 2014. Physicians will receive consolidated reports by August 2014. All reports will then be disclosed on a public website by September 30, 2014.

Where and How to Report?

The Sunshine Act requires the federal government to implement and maintain a web based reporting system. The reporting entities will submit web based reports that will include the physician's full name, business address, specialty, NPI, dates of any payments or transfers, and certain contextual information associated with the drug, device, biological or supply in question or the nature of the ownership or investment interest. Physicians may challenge these reports via an online portal for a period of 45 days after physicians receive the consolidated reports. This

challenge must first involve informal resolution activities between the physician and the applicable reporting party. If a resolution cannot be reached, the report will still be made public but will be flagged accordingly. Physicians may continue to seek corrective action with respect to a report for two years after it is publicly reported.

Why is the Sunshine Act Important?

The Sunshine Act is designed to promote transparency. Many healthcare professionals, and more importantly, patients and the public, have a view that monetary or other financial influence from manufacturers of drugs and devices tend to cause biased views about the benefits and risks of treatments and other alternatives. While the Sunshine Act is not designed to hamper innovation and discovery, it is the federal government's attempt to promote transparency and to allow everyone, including patients and physicians, to draw their own conclusions about the significance of any influence that drug or device manufacturers have over physicians.

Conclusion

Physicians should be prepared to address reports and disclosures under the Sunshine Act. After gaining a decent understanding of the requirements of the Sunshine Act, physicians should closely examine any arrangements in which they receive financial payments from manufacturers or otherwise maintain an ownership or investment interests in any of these entities. Physicians should then be proactive in contacting these entities and preemptively discussing each entity's intentions in making reports and disclosures. If possible, these discussions should include a candid conversation about the contents of any reports affecting the physician. Lastly, physicians should keep an eye on the federal government's activities associated with developing the reporting website. Once this website is developed, physicians should be given an opportunity to request and receive portal login information.

The Sunshine Act could have various repercussions to a physician's practice and keeping abreast of a physician's financial relationships with reporting entities and proactively managing these relationships is even more critical now. ■