The Physician Payments Sunshine Act

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The Physician Payments Sunshine Act (the Sunshine Act), part of the recently passed health reform legislation, contains new requirements which will shed light on potential conflicts of interest created by payments made to physicians and teaching hospitals by drug and medical device companies.[1] The Sunshine Act was first introduced in 2007 due to the belief that certain financial incentives may increase referrals for more costly care and could potentially interfere with the doctor-patient relationship. Patients will soon be able to access a website that lists all payments of value made each year by certain manufacturers to physicians and teaching hospitals throughout the country. Drug and device manufacturers should pay close attention to the forthcoming procedures and deadlines, because failure to report will result in significant monetary penalties. Physicians should also take notice, because physician-vendor relationships will soon be subject to enhanced public scrutiny.

Who is required to report?

The Sunshine Act requires "applicable manufacturers" to report various information to the Secretary of Health and Human Services (the Secretary). Applicable manufacturers include entities operating in the United States that produce a drug, device, biological, or medical supply for which payment is available under a federal health program (covered products).

The Sunshine Act also requires group purchasing organizations (GPOs) to report various information to the Secretary. GPOs include entities operating in the United States that purchase, arrange for, or negotiate the purchase of a covered product. Thus, manufacturers and GPOs are the only entities required to report under the Sunshine Act.

What is a payment or transfer of value?

The Sunshine Act defines payment or transfer of value broadly to include "a transfer of anything of value," including both cash and in-kind payments. However, payments of value do not include those made indirectly through a third party, in connection with an activity or service, where the manufacturer is unaware of the identity of the recipient. The following are also excluded from the reporting requirements:

- A payment or transfer of less than $10, unless the aggregate value of annual transfers to the recipient exceeds $100;
- Product samples that are not for sale and are intended to be used by patients;
- Educational materials that benefit patients or are intended to be used by patients;
- Devices loaned for less than 90 days so that a recipient can evaluate the device;
- Items or services provided under a contractual warranty as specified in a purchase or lease agreement;
- Anything of value, when the recipient is a patient;
- Discounts;
- In-kind items to provide charity care; and
- Dividends or profits from mutual funds or publicly traded securities.

Thus, payments or transfers of value generally include most cash and in-kind transfers, provided that the value of the transfer is greater than $10. This includes items such as airfare, hotel stays, honoraria, and many other "freebies" provided to physicians and teaching hospitals. However, the Sunshine Act makes it clear that certain payments or transfers, such as devices loaned for test purposes or donations made with the intent to be used towards charity care, do not need to be reported. Therefore, the reporting requirements may depend on the value of the transfer as well as its intended use or purpose.

What will be reported?

By October 1, 2011, the Secretary will establish a procedure to report payments of value and ownership interests. On March 31, 2013, and each year thereafter, manufacturers will be required to submit information, in electronic form, regarding payments made to physicians and teaching hospitals, including the name of the recipient, the business address, the National Provider Identifier, the amount of the payment or transfer, and the date of the transfer. The report must also include a description of the payment, indicating whether it was cash or a cash-equivalent, an in-kind item or service, or a return on investment, such as dividends or profits.

Manufacturers will also be required to describe the purpose of the transfer, noting for example, whether the payment was made

as a consulting fee, honoraria, or gift, or for entertainment, food, travel, or research. If the payment is related to marketing, education, or research of a specific covered product, then the name of the covered product must also be disclosed. Therefore, manufacturers must be sure to maintain accurate records regarding not only the identity of recipients, but also the reasons why particular payments were made.

Beginning March 31, 2013, and each year thereafter, manufacturers and GPOs will be required to disclose information regarding ownership and investment interests held by physicians. This does not include ownership or investment interests in publicly traded securities or mutual funds. The disclosure will include the dollar amount invested by each physician owner, the value of the investment, and its terms. Manufacturers and GPOs must also report payments made to physician owners, noting the identity of the physician, the date the payment was made, and a description regarding the nature and purpose of the payment or transfer.

What are the penalties for failure to report?

Entities that fail to comply will face a penalty for each payment or ownership interest that is not reported. Entities face strict liability and penalties ranging from $1,000 to $10,000 for each payment that is not reported, up to a maximum penalty of $150,000 each year. Manufacturers and GPOs that knowingly fail to report will face enhanced penalties of $10,000 to $100,000 per incident, up to $1 million each year.

How will the information be accessible?

On September 30, 2013, and June 30 each year thereafter, information gathered during the previous year will be displayed on a public website in a clear, searchable manner. The website will display the name and address of all disclosed recipients, the value and dates of the payments, and the purpose of the transfers. The website will also include information regarding enforcement activity, background information on physician-industry relationships, and additional information that should be helpful to consumers. Before any information is made public, manufacturers, GPOs, physicians, and teaching hospitals will be given no less than 45 days to review the information to confirm its accuracy.

Payments made by manufacturers for the purpose of conducting research or clinical investigations are subject to special publication rules. This information, while still accessible by the public on the new website, will be listed separately from all other information. Additionally, information regarding payments for product development and research in connection with new products will not be made public on the same date as all other payments. Instead, these payments will be made public on either the date the new product is approved by the Food and Drug Administration or four years after the payment was made, whichever is earlier.

What is the effect on existing state law?

The Sunshine Act preempts existing state law, but only to the extent that state law requires the same or less disclosure than required under the new federal law. This may be important, because a few states (such as Vermont and Massachusetts) have enacted similar payment disclosure acts, rather than waiting for federal action. Under the Sunshine Act, for example, if a state law requires disclosure of more information than required under the federal law or bans certain gifts or payments, then the state law is still valid. This allows states to require additional disclosure about payments made to physicians and sets a new federally imposed minimum standard on the practice.

Conclusion

Health reform's Physician Payments Sunshine Act requires increased disclosure by manufacturers and GPOs regarding certain payments and physician-vendor relationships. The reporting requirements fall squarely on manufacturers and GPOs, rather than physicians or other health care providers. However, an array of potentially sensitive information—the identity of physicians and teaching hospitals receiving payments, the purpose of certain payments, the amount of the payments, and the details of physician investments—will soon be made available for public review. The Sunshine Act does not prohibit transfers of value, but instead increases transparency, leaving health care decision-making in the hands of consumers, who may use the new tools and information made available under the Sunshine Act to make truly informed decisions. ■

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The views and opinions expressed in this article are those of the authors and do not necessarily reflect those of Sills Cummis & Gross PC.

1 Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010).