The Physician Payment Sunshine Act

Collaboration among physicians, teaching hospitals, and industry manufacturers contributes to the wealth of drugs and devices available to physicians and patients today. Questions exist as to how much collaboration is beneficial and where the line may get crossed regarding conflict of interest. Do these collaborations influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care?

On December 14, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule that addresses the implementation of the Physician Payment Sunshine Act (Sunshine Act).¹ In summary, the Sunshine Act, a component of the Patient Protection and Affordable Care Act (PPACA), requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Secretary of Health and Human Services certain payments or transfers of value provided to physicians or teaching hospitals. Teaching hospitals are defined as any institution that received direct graduate medical education payment or indirect medical education payment. In addition, applicable manufacturers and group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. The Secretary is required to publish this information on a public Web site.

The Sunshine Act mandates that applicable manufacturers and GPOs will be responsible for reporting a variety of elements on the payments that are made to physicians and teaching hospitals. They will need to report name of the covered physician or teaching hospital; business address; specialty and National Provider Identifier; date of payment; associated covered drug, device, biological, or medical supply (if applicable); form of payment; and nature of payment. Forms of payment include cash or cash equivalent, in-kind items or services, stock, stock options, or other. Nature of payment includes consulting fees, compensation for services other than consulting, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalty or license, current or prospective ownership or investment interest, direct compensation for serving as faculty or as a speaker for a medical education program, and grants.

Under the PPACA, applicable manufacturers and GPOs were to begin collection of this information on January 1, 2012, but instead will now be able to wait until the publication of the final rule. Manufacturers will most likely have a 90-day preparation period once the final rule is published to start collecting the required information. Most likely, a final rule will be published before the end of 2012 and data will be collected for part of 2012 and reported to CMS by the required date of March 31, 2013.

The data collection and reporting obligations imposed by the Sunshine Act should not be taken lightly, because failure to comply can result in significant civil monetary penalties for applicable manufacturers and GPOs, ranging from \$1,000 to \$10,000 for each payment or other transfer of value that is not reported (up to a maximum of \$150,000), and from \$10,000 to \$100,000 for each knowing failure to report (up to a maximum of \$1 million).

Some interesting information for physicians and teaching hospitals:

- If a physician wishes to donate their honorarium to a favorite charity, this payment would still be reported under the name of the covered recipient since they are made at the request of, or designated on behalf of, a covered recipient as required in section 1128G(a)(1)(A). CMS is also proposing that applicable manufacturers report the name of the favorite charity that received the payment at the request of the physician. CMS believes this will maximize transparency about the details of the payment.

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- CMS has proposed that applicable manufacturers do not need to report any offerings of buffet meals, snacks or coffee at booths at conferences or similar events where it would be difficult to definitively establish who has accepted the offerings. On the other hand, bagels or donuts that are brought into a doctor's office or to a teaching hospital by a manufacturer representative will be reported despite not knowing who actually eats this food which in many cases may be eaten by office and hospital staff, not the physicians themselves.
- It had originally been thought that third-party groups such as continuing medical education (CME) providers, professional medical associations, patient advocacy groups, and other non-profit groups would not be impacted by the Sunshine Act. With the issuing of the Proposed Rule, it is now thought that if these groups receive an educational or research grant, or any other kind of payment or transfer of value, and they use any portion towards a physician or teaching hospital—and the applicable manufacturer is “aware” of the identity of the physician or teaching hospital—then the manufacturer is required to report how much the organization paid the covered recipient. There are many details around this area that must be clarified by CMS.
- CMS has proposed that applicable manufacturers and GPOs should provide physicians and hospitals with the data they plan on submitting to CMS so that physicians and hospitals can verify the correctness and make any changes. Physicians and teaching hospital compliance officers will need to take time to review the data to make sure they are being represented correctly.

Some of the drive behind this initiative is the belief that patients will benefit by having access to this information. CMS and others believe that patients will take the time to look up their physicians in this database and see how they have interacted with applicable manufacturers and GPOs. Will patients care that their doctor received payment to participate in clinical research or if they had a \$5 turkey sandwich that was brought into their office by a sales representative? It remains to be seen if and how patients will use this information.

Physicians and teaching hospitals must ask themselves some questions regarding the future implications of this information being publicly available and the perceptions others will form based on it. Will physicians be less likely to participate in clinical research with manufacturers because of the need of manufacturers to report the payment? Will physicians and teaching hospitals be less likely to participate in industry-sponsored CME? If manufacturers change the ways they sponsor clinical research and CME, will the care patients receive be affected? Will the possible change in collaboration habits slow down the development of new drugs and devices patients need?

Financial ties alone do not signify an inappropriate relationship, and disclosure alone is not sufficient to differentiate beneficial, legitimate financial relationships from those that create conflict of interest. Whether the Physician Payment Sunshine Act can balance discouraging inappropriate relationships without harming constructive ones that benefit both patients and providers remains to be seen.

Reference

1. Medicare, Medicaid, Children's Health Insurance Programs; transparency reports and reporting of physician ownership or investment interests. Fed Regist 2011;76(243):78742–78773. To be codified at 42 CFR §402 and §403.