Health Law Alert: Just in Time for the New Year: CMS Delivers the Sunshine Act

December 29, 2011

The Centers for Medicare and Medicaid Services (CMS) has released a proposed rule implementing the Physician Payments Sunshine Act. The Sunshine Act requires drug, device, and other manufacturers and group purchasing organizations (GPOs) to publicly disclose certain financial relationships with physicians and teaching hospitals. The idea is that by making these relationships transparent, consumers will be able to judge whether their providers have any conflicts of interest with respect to the drugs, devices, and other products they prescribe or recommend. CMS will accept comments on the proposed rule through February 17, 2012, and will publish a final rule in 2012.

Highlights of the Sunshine Act

The bulk of the burden created under the proposed rule will fall on covered manufacturers and GPOs because these are the organizations that will need to file reports with CMS. Physicians and teaching hospitals should understand, however, that CMS intends for a significant amount of information about their financial relationships with those organizations to be publicly available, even where the amount in question is as small as $10. All of this information is intended to be easily searchable by consumers. It will also of course be available to regulators charged with enforcing the Anti-kickback Statute and other important laws.

Who Must Report? Manufacturers and Group Purchasing Organizations

The regulations define manufacturers as any entity involved in the production or manufacturing of drugs, devices, biologicals, or medical supplies if those products are covered by Medicare, Medicaid, or the Children's Health Insurance Program. The requirements will apply to any manufacturer of covered products sold or distributed in the U.S., regardless of where the products are produced. GPOs that purchase or arrange for the purchase of drugs, devices, or medical supplies for another entity are also subject to the Sunshine Act.

Covered Recipients and Reportable "Transfers of Value"

CMS proposes to define "payment or other transfer of value" broadly to capture almost anything of value given to a physician or teaching hospital. Although exceptions exist for things like educational materials and product samples intended for patient use, CMS' definition is intended to cover most transfers of value that exceed $10, as well as transfers below that amount if the annual aggregate exceeds $100. These amounts

will be adjusted in future years based on changes in the Consumer Price Index.

The reports will need to include a large amount of information, including the name and identifying information for the manufacturer making the payment, the doctor or teaching hospital receiving it, the amount of each payment, and the drug or device associated with the payment or transfer of value. In addition, manufactures and GPOs are required to define the "form" and "nature" of payments into one of several specific categories. For example, a manufacturer would need to indicate whether a cash payment was a "consulting fee," "honoraria," or "gift." If the payment falls into multiple categories—for example a physician receives a consulting fee and travel expenses—CMS proposes that each payment should be disclosed separately. CMS will make most of the information that is disclosed publically available in an online searchable database. Reporting organizations will have to attest to the accuracy and completeness of the information they provide. These organizations, and the physicians and teaching hospitals about whom the reports are made, will have a 45-day window after reporting (before CMS makes the information publicly available) to correct any errors that are discovered.

Manufacturers and GPOs will also be required to disclose whether physicians or their immediate family members have an ownership or investment interest in the entity itself. These organizations will need to disclose a variety of information about any such investment interests, including the dollar amount invested and the value and terms of each ownership or investment interest. The proposed rule indicates that investment interests will be defined in a similar manner as in the Stark self-referral law.

Penalties
Violators of the reporting requirements will be subject to civil monetary penalties, capped at $150,000 annually for failing to report. The most serious violations, those that involve "knowing" failures to report, may be subject to the maximum penalty of $1,000,000. CMS and the Office of Inspector General will have audit authority over manufacturers' and GPOs' records to ensure compliance with the reporting requirements.

Modified Reporting Deadlines
Until the Proposed Rule was released, the industry was expected to begin data collection starting January 1, 2012, and report it on March 31, 2013. CMS has now indicated that manufacturers and GPOs do not need to begin data collection until after final regulations are issued. Data submission is scheduled to occur on the original date of March 31, 2013, but CMS is proposing that only a partial year's data will need to be reported. In future years, reports will need to be filed by the 90th calendar day of each year. Manufacturers and GPOs will have to register with CMS prior to being able to file their reports.

The modified deadline allows those organizations who have been working to collect the required data the option to be proactively transparent by reporting all of the required financial relationships for 2012. For those who have postponed collecting the required information until the guidelines were released, the delay offers

an opportunity to prepare for compliance in 2013.

Report, Rinse, Repeat

The Sunshine Act is just one of many steps taken under 2010's Affordable Care Act that were designed to increase transparency in health care. Regulators have long been concerned that payments from manufactures to providers can create conflicts of interest by influencing research, education, and clinical decision-making in ways that negatively affect patient care and lead to increased health care costs. While the disclosure of these relationships will not necessarily flag every inappropriate financial arrangement—and while most relationships that are disclosed are likely to be completely appropriate—the transparency is intended to give the public an opportunity to scrutinize those relationships that are at least potentially suspect. Given the low threshold required for reporting, and the broad scope of the Sunshine Act's application, some wonder how effective this requirement will be as a tool for raising public awareness.

Prepare for the Final Rule: Speak out and Get Compliant

The proposed regulations make it clear that compliance with the Sunshine Act will require manufacturers and GPOs to have an in-depth knowledge of the Act's provisions and a dedicated compliance program. Given the "sunshine" that will be infused on to their relationships with these companies, physicians and teaching hospitals will need to be comfortable with enhanced public awareness of their activities. CMS acknowledges the costs the Act will impose on the industry and its commentary throughout the proposed rule indicates that the agency is considering alternatives to a number of its proposals. Thus, submitting comments would be in the best interest of entities that are most affected by the burden of the reporting requirements. CMS has often noted that the best way for it to understand how organizations are impacted by its proposals is to hear directly from those parties, with concrete examples being the most effective way of educating CMS about the burdens of new regulatory requirements.

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