The Physician Payment Sunshine Act: An Update

What physicians and industry should know about the final rule.

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On February 1, 2013, under tremendous pressure from Congress, the Centers for Medicare and Medicaid Services (CMS) issued its final rule regarding the implementation of the Physician Payment Sunshine Act, a portion of the 2010 Affordable Care Act that mandates disclosure of payments from industry to health care providers. The final rule establishes new dates for manufacturers' and other entities' initial collection of data and their submission to CMS; it also provides definitions for and clarification of several key aspects of the reporting scheme.

In connection with the proposed rule, CMS received and responded to a total of 337 public comments, ranging from, "Scrap this legislation," which obviously CMS does not have the ability to do, to, "It doesn't go far enough, and we should have even more transparency on relationships between industry and health care providers." Any rule with that many responders is like making a sausage because it requires an administration to attempt to balance all of those comments and various stakeholders.

This article describes several features of this complex legislation in an effort to elucidate the effect it will have on physicians, their practices, and their relationships with industry.

DATA COLLECTION AND REPORTING

Ultimately, the Sunshine Act will require manufacturers and applicable group purchasing organizations (GPOs) to begin collecting the required data on August 1, 2013. The first report will be due to CMS by March 31, 2014, and the first time the data will be posted to the public website will be September of next year. In addition, there must be aggregate reports, which go by company and will be submitted to Congress as well as to the states.

Under the Sunshine Act, applicable manufacturers are required to report direct and indirect payments and other transfers of value provided to covered recipients or in accordance with the recipients' direction. At 1 point, I had been hearing some physicians suggest that, if you set up a limited liability company (LLC) and ask the manufacturers to pay the fees you receive from them into the LLC, those payments would be protected. However, those payments are not protected—they would have to be reported, as would the name of the LLC.

The Sunshine Act also requires manufacturers and applicable GPOs to report ownership and investment interests. The legislation does not just concern compensation but extends to ownership and investment for physicians as well as their immediate family members. In addition, the term *immediate family members* goes pretty deep—further than just spouse and children—to include grandparents, father-in-law, daughter-in-law, grandparent's spouse, etc.

COVERED RECIPIENTS

The "covered recipients" referred to in the Sunshine Act include MDs, DOs, and ODs. Physicians who are bona fide employees of a manufacturer are excluded, and the Internal Revenue Service test is used to determine that. Therefore, companies cannot use an employment agreement rather than an independent contractor agreement and call someone an employee to try to get around the reporting requirements. Teaching hospitals are covered recipients as well.

COVERED ENTITIES

The Sunshine Act applies to manufacturers that operate in the United States and are engaged in the production, sale, or distribution of a covered drug, device, biologic, or medical supply. By definition, a covered drug is a product that is paid for by Medicare, Medicaid, or the Children's Health Insurance Program and requires a prescription or premarket approval or 510(k) clearance from the US Food and Drug Administration. Over-the-counter drugs and devices that do not require any kind of premarket approval are exempted.

Entities under common ownership with the developer that provides some assistance are covered as well. So, if the manufacturer has a subsidiary that is a manufacturer or a subsidiary that does sales and marketing, as long as they have a common parent and are working together

toward promotion of the product, they would both be captured by the rule.

REPORTED TRANSFERS OF VALUE

CMS defines a payment as any transaction that has a discernable value made at the request of or on the behalf of a covered recipient (a physician). This includes payments to a group practice, so if you decide that a payment for consulting work with a company is going to be paid to your group rather than to an individual physician, that payment must still be reported but is done so at the level of the physician who actually received it. There were a number of comments from physician organizations that expressed angst over a group being named the recipient of a payment because other physicians in the group may not want to be on a report. Therefore, CMS agreed that the payment would only be in the name of the direct recipient.

Indirect payments are those made through third parties, when a manufacturer or GPO causes a third party to provide the value to the physician. For example, an unrestricted educational grant goes to a third party, but there is a mutual understanding between the company and the third party that the money will go to Dr. Jones; that transfer of value would be captured under the indirect payment requirements. For ownership or investment, stock and stock options get reported, only once the stock options have been exercised; prior to that, they are just considered compensation. Partnerships, LLC membership, loans, bonds, and anything direct or indirect through debt or equity are other types of ownership interests that must be reported as well.

There are exceptions to the ownership reporting requirements. Ownership and investment in a public traded security or mutual fund does not need to be reported. Also exempted are interests that arise from a retirement plan that you may acquire having been a physician employee of a covered entity, stock options and convertible securities received as compensation until they have been exercised, unsecured loans, and interests truly unknown to a manufacturer or GPO. For the purpose of the Sunshine Act, the definition of the word *know* is the same as for the False Claims Act, so it covers not just actual knowledge; it also means reckless disregard of the truth. Therefore, you cannot say, "I did not know," when, for all intents and purposes, anyone could have assumed that company would have known about that ownership interest.

The relevant forms of payment include basically any cash or cash equivalent, items of services, stocks, dividends, profits, or other returns on investment. The various types of payment that are received must be reported in categories. Within each category, there are specialized rules, even down to how food and beverages are reported.

The actual reporting that will be provided to CMS includes the name of the physician, his or her business address, his or her National Provider Identifier, his or her Medicare number, the medical license number from at least one state in which he or she practices, and his or her specialty. The specialty will be listed as however the physician is categorized for Medicare purposes. The form of the payment, the category, the amount, the date of the transfer, and the product that it relates to are also listed. The identity of any third party involved in a transaction will also be reported.

There are special reporting rules regarding financial relationships around research and continuing medical education. These regulations are highly detailed and complex, but if you are a researcher or an investigator for a company, it is imperative that you take time to understand these research rules. Companies and GPOs face civil monetary penalties for failure to report accurately or completely.

EXCLUSIONS FROM REPORTING

There are a few exclusions from reporting, including payments of less than $10, unless, over a year, the aggregate in that particular category totals $100. So, if you bring someone 12 $9 lunches, ultimately, all of those payments must be reported. Indirect payments for a physician whose identity is unknown as well as product samples or vouchers that are for patient benefit only will not have to be reported. Patient education materials that are truly and directly beneficial to patients and are not promotional in nature are excluded as well. For trial equipment and disposable supplies, if a piece of capital equipment is placed

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This year, global technology company MMIS Inc. reported the results of its third annual survey of doctors and their knowledge of the Physician Payment Sunshine Act. The company found that, of the 1000-plus physicians surveyed, more than half of respondents admitted they did not know that the law requires pharmaceutical and medical device companies to report on expenditures annually or that the information will be available in a publicly searchable database. According to MMIS, this year's survey results reflect a 5% increase in unfamiliarity with the law's provisions by doctors in all types of care locations, from teaching hospitals to private practices.

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in a physician's office or in an ambulatory surgery center to be tested, that trial equipment and sufficient disposables can be kept for up to 90 days without the value having to be reported. If the machine stays for day 91, the value of having that capital equipment and those disposables for days 91 and beyond must be reported. For items and services under contractual warranty, the value of that warranty is not required to be reported. Actual discounts and rebates are also exempt from reporting.

PUBLIC DATABASE

There will be a 45-day period of review before the reported data are published on the public website. This period was requested by physicians and was not in the initial proposed rule. Once the manufacturer submits its information and the government develops the database, physicians will have the ability to register onto the website and review what has been reported by the various manufacturers and GPOs. If the physician disagrees with what has been reported, then that dispute must be resolved with the manufacturer within 15 days. So, in total, you have 45 days to review and 15 days to resolve any potential disputes. If the dispute cannot be resolved, the information will still be posted in the database, but it will be notated that there was a dispute between the manufacturer and the health care professional.

The website will be searchable and fully downloadable. It will contain information regarding relationships between manufacturers and physicians and the positive aspects of these collaborations. There were also a lot of requests that researchers be able to have access to additional information that will not be on the public website, and that is still under negotiation.

CONCLUSION

Covered recipients should be aware the some aspects of their dealings with industry will be reported and publicized. Manufacturers and GPOs will report on a range of compensation items, including consulting fees, gifts, honoraria, travel and lodging, education, royalties, grants, etc. There will be a 45-day review period and 15-day period to resolve disputes, and covered recipients can register with CMS to receive information for review. Both health care and industry professionals should familiarize themselves with the provisions of this legislation and its potential effect on their relationships. ■

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