

Shining a light on the Sunshine Act

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Every month, *Dermatology World* covers legal issues in *Legally Speaking*. This month's author, Daniel F. Shay, Esq., is a health care attorney at Alice G. Gosfield and Associates, P.C.

The “Sunshine Act” as it has come to be known (stemming from Sen. Charles Grassley’s position that sunshine is the best disinfectant) is one of the more recent additions to the constellation of rules intended to ensure that the patient-physician relationship is untarnished. This article examines the background of the Sunshine Act, addresses how it is applied and its general requirements, addresses how data is actually reported and physicians’ ability to dispute inaccurate information, and examines the Act’s impact on dermatologists.

Background and what gets reported

Although it was originally proposed in 2007, the Physician Payment Sunshine Act of 2009 was passed as part of the Patient Protection and Affordable Care Act of 2009, with regulations published in 2013. The Act and its regulations generally require device and pharmaceutical manufacturers and group purchasing organizations (GPOs) to report to the Centers for Medicare and Medicaid Services (CMS) on: (1) direct and indirect payments or other transfers of value that are provided by the manufacturer or GPO to “covered recipients” or to third parties on behalf of such covered recipients during the previous calendar year, and (2) ownership and investment interests in the manufacturer or GPO held by “physicians” (as defined under Medicare, meaning any MD or DO, dentists and dental surgeons, podiatrists, optometrists, and chiropractors) or their immediate family members during the prior calendar year. “Covered recipients” include physicians (except those employed by the manufacturer reporting the payments) and teaching hospitals.

The type of data that must be reported include: the recipient’s name and primary business address; for physicians, the physician’s specialty, National

Provider Identifier number, state professional license number and the state where the physician is licensed; the amount and date of each payment; the form and nature of the payment; the name of the related drug, device, or biological or medical supply, as well as its therapeutic area or product category; payments to third parties; and, payments to physician owners or investors, or their immediate family members. The information reported is posted on a website maintained by CMS,

openpaymentsdata.cms.gov.

The reportable form of payment (or transfer of value) is categorized as: cash or cash equivalents; in-kind items or services; stock; stock options; other ownership interests; dividends, profits, or returns on investment. Reporting entities must also report the nature of the payment or transfer or value, which is categorized as: consulting fees; compensation for other services (e.g. serving as faculty or a speaker at an event other than a continuing education program); honoraria; gifts; entertainment; food and beverage; travel and lodging; education; research; charitable contributions; royalties or licenses; current or prospective ownership or investment interests; compensation for serving as a faculty or as a speaker for accredited or certified continuing education programs (as well as a separate category for unaccredited and non-certified programs); and grants.

A manufacturer or GPO’s failure to report can result in penalties of a minimum of \$1,000 and a maximum of \$10,000 per payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely, with total annual penalties capped at \$150,000. Knowing failures, on the other hand, are penalized much more severely, with a minimum penalty of \$10,000, a maximum of \$100,000, and an annual cap of \$1 million.

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How data appear online and disputes over data

The good news for physicians is that there are no reporting requirements for them — and thus no associated penalties for failing to report — only manufacturers and GPOs must report. The other news is that information about the money they receive from industry is now a matter of public record. The “Open Payments” website allows users to search by the physician’s name alone, or by name, city, state, street address, and/or specialty. Actual data for a given physician includes name, street address, and specialty (e.g., “Allopathic or Osteopathic Physicians/Dermatology”).

The data also include information on payments broken down by reporting year. The payment information includes the total dollar amount of payments made during the year, the total number of transactions during the year, and includes the following sub-categories: research payments, ownership and investment interests, associated research, and disputed payments. The site also indicates whether the total dollar amount and total number of transactions were above or below the national mean and national median, as well as the specialty mean and specialty median. Users can also examine the specific payments to see the reporting entities that made the payments, the total amount per entity, the total number of payments per entity, the type of payment (e.g., food and beverage, education, etc.), and the date of the specific payments.

For example, for the 2016 program year (reported in 2017), a dermatologist may have a report indicating that he received total payments of \$4,545.00, with a total number of 43 payments, which comparatively states he also received \$1,271.29 and 25 payments above the national mean, but below the specialty mean by \$322.44 and above the specialty mean by nine payments.

The user could also see how the totals compare to national and specialty medians. A user could dig deeper into the data to determine what kind of payments were made, and might see that the physician was paid these amounts solely for food and beverage, with most payments being small amounts paid by a wide range of pharmaceutical companies. By contrast, an oncologist might have much higher payments in a given year, falling above the national mean, but still well below the specialty mean, and the user might see that most of the money paid was for consulting fees, with a smattering of food and beverage payments, and travel and lodging payments, with almost all of the payments coming from a single pharmaceutical company.

Physicians are permitted to dispute payment information, but must do so in the calendar year in which the information is reported. Data is reported and published each year on June 30, and a second time as a “refresh publication” approximately six months later with updated data. Physicians are given 45 days to review and dispute records prior to initial publication, and an additional 15 days is provided for reporting entities to correct data. If a dispute is not resolved during the review and correction period, it will be published as a disputed payment at the time of initial publication. If a dispute is resolved between the June 30 publication date and the date of the refresh publication, it will be corrected in the database. Disputes that are resolved after the end of the calendar year may be published as corrected in the initial publication the following year. Disputes unresolved during the calendar year will remain as disputes in the subsequent calendar year’s initial publication, unless they are resolved prior to initial publication.

Although CMS provides a website through which physicians and reporting entities may initi-

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ate and track disputes, CMS does not mediate disputes; disputes are handled outside of the Open Payments system. (For more information on how to initiate and navigate disputes, see CMS' website, www.cms.gov/OpenPayments/Program-Participants/Physicians-and-Teaching-Hospitals/Review-and-Dispute.html.) Disputes may be resolved with changes, or without changes. For example, a physician might dispute two separate payments, with one being revised because it was incorrect, and the other payment remaining unchanged because the parties came to an agreement that the report was correct.

Impact on physicians

The actual impact of the Sunshine Act on physicians is debatable. While it is clear that educational payments by reporting entities for continuing medical education have plummeted, it is worth remembering that the Sunshine Act was passed in the midst of the financial crisis, at a time when companies may have already been inclined to tighten their belts; and physicians began to turn toward more “on demand” educational resources, such as CME webinars. However, the halcyon days of Big Pharma-sponsored Caribbean CME conferences are certainly long gone.

Beyond these impacts, however, it remains unclear just how much disinfecting the Sunshine Act has actually accomplished, or whether there was much to disinfect in the first place. The Sunshine Act does not penalize the underlying relationships between physicians and industry (although other laws such as Stark and the anti-kickback statute might impact payments received from industry), and only penalizes failure to report — with those penalties applying only to reporting entities. Moreover, the nature of the Open Payments website shifts responsibility to patients to review their physicians' information, determine just how troubled they are by what they see, and whether to raise the matter with their physicians. Even an initial moment of “sticker shock” at discovering that your physician has received some \$200,000 from industry might not result in much concern if, after examining the nature of the payments, it becomes clear that the physician has a license agreement with a manufacturer — suggesting that the physician may have licensed to the company a device he or she designed, and received payment for it. In other

instances, all that patients may discover is a litany of \$15-35 payments for food and beverages, which may not elicit much more than a yawn.

Within the dermatology specialty, a 2016 article published in *JAMA Dermatology* reported that in 2014, 8,333 dermatologists received 208,613 payments, for a total of \$34 million (152(12):1307-1313). Of those receiving payments, 78% received less than \$1,000, 63% received less than \$500, and 25% received less than \$100, with most individual payments being worth less than \$50. Most payments received were made by pharmaceutical companies. The \$34 million figure amounted to less than 1% of the \$6.49 billion in industry payments to physicians during the same year. Payments took the form of speaking fees, consulting fees, research activities, food and beverage services, and royalty and licensing fees. Food and beverage services made up the greatest number of individual payments, while research, consulting, and royalty and licensing fees were the highest dollar payouts. Based on this information, it appears that dermatologists are relatively “small potatoes” in terms of specialties with strong ties to industry and that receive large payments. Thus, patients may not be particularly troubled by what they see on the Open Payments website about their dermatologist.

Conclusion

Ultimately, the Sunshine Act simply provides additional data by which a patient may evaluate whether their doctor is trustworthy. For that to happen, however, a patient has to be aware of the existence of the Open Payments website in the first place, then be curious enough to examine the information, understand the information presented, determine that the information they find warrants concern, and then speak to the physician about it. If you have never received a question from a patient about your ties to industry, then the Sunshine Act may be much ado about nothing. Dermatologists should monitor the data submitted about them for accuracy, and dispute incorrect data when they find it; but at the end of the day the Sunshine Act may be less important to your relationships with patients than a good bedside manner, courteous and helpful staff, and the patient's own sense that you have their interests as your primary duty. *dw*