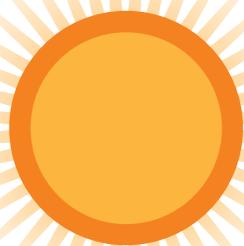


The Sunshine Act: How to Avoid Getting Burned



On Aug. 1, 2013, the Centers for Medicare & Medicaid Services (CMS) began implementing the Physician Payments Sunshine Act.

Part of the Affordable Care Act, the Sunshine Act requires pharmaceutical, medical device manufacturers, and group purchasing organizations (GPOs) to report all cash payments, gifts, and other “transfers of value” made to physicians and teaching hospitals each year. The law is designed to make more transparent the financial relationships that sometimes develop between physicians and industry suppliers.¹

While the reporting requirements don’t apply to physicians themselves, physicians should watch for errors in the reported data and be prepared to discuss the information with patients.

Here’s what we know about the law and how it will affect family physicians going forward:

Q: What payments and transfers of value are being reported on physicians and practices, and what is excluded?

A: The Sunshine Act covers various forms of payment, including cash or cash equivalent; in-kind items or services; stocks, stock options, or other ownership interest; as well as dividends, profits, or other returns on investments. CMS requires manufacturers and GPOs to also report the “nature of payment.” The following are subject to reporting: consulting fees; compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education

program; honoraria; gifts; food and beverages; entertainment; travel and lodging; research activities; charitable contributions; royalties or licenses; current or prospective ownership or investment interests; compensation for serving as faculty or as a speaker for certain continuing education programs; grants; space rental; or teaching hospital facility fees.

Excluded from the reporting requirements are payments or other transfers of value of less than \$10, except when the total annual value of payments or other transfers of value provided to a physician exceeds \$100; educational materials that directly benefit patients or are intended for patient use; discounts, including rebates; in-kind items for the provision of charity care; product samples (coupons and vouchers); short-term loans (defined as no more than 90 days) of a covered medical device; contractual warranties; payments received when the physician is acting as a patient; the provision of healthcare; payments to nonmedical professionals; dividends or other profit distributions from, or ownership or investment interest in, publicly traded securities or mutual funds; payments as a result of civil or criminal actions or administrative proceedings; and indirect payments or other transfers of value where the applicable manufacturer is unaware of the identity of the physician.

Q: How are physicians notified if something has been reported about them and where is that information displayed?

A: CMS is required to provide information to physicians before the annual transparency reports are made public.

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Physicians will be able to view the information through an online portal. Physicians may also register with CMS to receive email notification about the review process.

Q: Once these payments are reported in a public database, how can physicians check the accuracy of that information and fix any errors?

A: It is imperative that physicians access the information reported about them and review it carefully. The data will be provided to CMS each year by March 31. CMS will provide physicians only 45 days to review the data before CMS makes the information available to the public. If the physician agrees with the information reported, the physician may either electronically certify that the information reported is accurate or do nothing, in which case it will be reported as-is. The physician can initiate a dispute using the online portal, and the two sides will have 15 days to resolve it. After that date, the two sides can continue to work on a resolution, but the original data will be published, albeit flagged that it is disputed.

Q: What should an independent physician or practice do right now to prepare as the Act goes into effect?

A: First and foremost, physicians must become familiar with the new federal Sunshine Act rules as well as any applicable state requirements. Someone in the practice should be responsible for assuring that physicians have the latest information on developments associated with the Sunshine Act. Helpful information can be found at <http://go.cms.gov/openpayments>, including an opportunity to sign-up to receive ongoing updates via email.

Office administrative staff should be educated on the importance of the new Sunshine Act requirements and the need to maintain a log of all sales rep interactions. If practices do not already have a sales rep visitation policy, one should be developed and staff trained on its terms.

Some practices are revamping their existing sales rep visitation policies by limiting visits to certain days and times when patient waiting room volume is typically low. Physicians should keep records of all payments and other transfers of value received from manufacturers or GPOs and make it a practice to ask if funds or transfers of value that are received from companies or their sales representatives are to be reported under the Sunshine Act. This serves not only as a check on what might be reported by the company, but may offer insight as to the compliance practices of those companies and help to avoid unscrupulous individuals or entities.

Finally, be aware of the key dates for reporting and schedule time in April or May of each year to review the information reported when it becomes available. Manufacturers and GPOs will use the National Provider Identifier (NPI) database to identify physicians and other covered recipients, so physicians should also make sure their NPI information is current.

Q: How are the requirements different for employed physicians, particularly those who work in a hospital?

A: The Sunshine Act makes no distinction between employed and private practice physicians in terms of what it defines as a “covered recipient.” Teaching hospitals are considered “covered recipients” on their own, meaning any payments made to a physician who is employed as medical faculty will be reported under the hospital’s name and not that of the physician. However, if the physician, in his or her private capacity, consults, serves on a scientific advisory board, or engages in other compensated activity for manufacturers, then the details and purpose of that income will be reported to CMS and displayed on the public website under the physi-

WHAT ABOUT MEALS?

For CME conferences in which meals are provided to a large group of attendees, making it difficult to establish the identities of the physicians who received the meal or snack, reporting will not be required.

But all other meals, such as lunches provided by sales representatives at physician offices or drug company-sponsored dinners, represent a “transfer of value” that must be reported if the cost is \$10 or more per person. Physicians who do not wish to participate in a meal may decline and should not be included in reporting on that meal.

The payment amount allocated to each physician is the total value of the items provided divided by the total number of individuals consuming them, including all office staff and other personnel even if such individuals are not considered “covered recipients.”

Practices may want to alert their sales reps to their desire to keep meal costs below \$10 a person. For organized events, practices can ask staff to sign-up for the meal in advance, so that the practice can notify the rep the allowable budget based on the number of attendees expected. Remember, however, that even if individual meals are kept below \$10 per recipient, more than 10 of those meals over the course of the year may exceed \$100 and result in a physician being reported anyway.

This strategy will be more difficult for food dropped off as the sales rep doesn’t know how many people will be consuming it and will likely divide the total cost of the food by the number of physicians and other staff in the practice. Practices should decide now whether they want to continue accepting these kinds of lunches from their sales reps.

■ The Sunshine Act is meant to provide transparency to financial relationships between physicians and manufacturers.

■ Physicians will have a limited time to review and dispute payments attributed to them.

■ The Sunshine Act excludes residents, midlevel providers, and other practice staff.

cian's own NPI. These physicians, not the hospital where they teach, must register with CMS to access the data reported and will be responsible for contacting manufacturers to address any discrepancies. Medical faculty who serve as principal investigators should check with their institutions for additional rules dealing with manufacturer payments tied to research.

Q: Who is excluded from the Sunshine Act?

A: Residents, physician assistants (PAs), nurse practitioners (NPs), certified midwives, and other similar nonphysician providers are excluded from the Sunshine Act. Note that payments actually directed to a physician but "received" by a PA or NP must be reported by the manufacturer as a payment to the physician.

Q: How does this affect CME-related payments?

A: CMS excluded certain CME-related payments from the Sunshine Act reporting requirements. A payment made to a speaker

at a continuing education program does not need to be reported under the following conditions:

- The program meets the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP, or ADA,
- An applicable manufacturer neither selects the speaker nor provides a pool of preferred speakers to the third party organizer,
- The manufacturer does not directly pay the speaker.

Additional questions and answers about the Sunshine Act are included in the online version of this article at <http://www.aafp.org/fpm/2013/0900/p8.html>. **FPM**

1. Agrawal S, Brennan N, Budetti P. The Sunshine Act – Effects on physicians. *N Engl J Med.* 2013;368(22):2054-2057.

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