

Shedding Light on What the Sunshine Act Will Mean for Physicians

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The “Sunshine Act” requires manufacturers of drugs, devices, biological, and medical supplies to report to U.S. Department of Health and Human Services (HHS) certain payments and “transfers of value” to physicians and teaching hospitals. These “transparency reports” are required beginning in March 2013, and will cover the previous calendar year’s payments. The following Q and As are designed to help ensure physicians understand the new law and what it means to them.

What is the Sunshine Act?

The Sunshine Act is the popular name for Section 6002 of the Patient Protection and Affordable Care Act (PPACA), which was signed into law by President Obama on March 23, 2010. As noted above, the law requires manufacturers of drugs, devices, biological, and medical supplies to report to HHS certain payments and “transfers of value” to physicians and teaching hospitals. These are referred to as “transparency reports.” It also requires these manufacturers and group purchasing organizations (GPOs), including those owned by physicians, to submit reports regarding ownership or investment interests held by physicians or their immediate family members. The Sunshine Act does not prohibit the reported payments or ownership interests.



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How will the Sunshine Act be implemented?

The Secretary of the HHS is required to write rules to implement this reporting scheme. The Centers for Medicare and Medicaid Services (CMS) published proposed rules December 19, 2011.

What amounts trigger reporting?

Transparency reports are required for a single payment or transfer worth \$10 or more or cumulative payments/transfers of \$100 or more in a calendar year. However, determining when the \$10/\$100 reporting threshold has been triggered is not always easy. For example, if a sales rep brings \$25 worth of bagels and coffee to a solo physician’s office for a meeting, the reportable “per covered recipient cost” is \$25 because there is only 1 physician. Since this is above the \$10 minimum threshold for reporting, this must be reported. However, if the same bagels went to a group of 5 physicians, the per-covered recipient cost would be \$5, and this “payment” would not need to be reported.

CMS proposes not requiring transparency reports of buffet meals, snacks, or coffee at conference booths and similar events where it would be difficult to establish the identities of the individuals who accept the offerings.

This threshold is lower than some state sunshine-type reporting requirements and far lower than the \$5000 threshold used by the National Institutes of Health in its regulations governing disclosure of its grantees’ financial conflicts of interest. These numbers will be adjusted annually for inflation.

What ownership/investment interests are reportable?

Ownership/investment interests are defined broadly as direct or indirect debt, equity or other interests, including stock options (other than those received as compensation, until they are exercised), partnership shares, LLC memberships, loans, bonds, and other financial instruments.

The Sunshine Act and the rule make a key distinction between manufacturer reports of payments/transfers on the one hand and manufacturer/GPO reports of ownership/investment interests on the other hand. When a manufacturer makes a payment to an employed physician, the payment is not reportable. However, the ownership and investment interests of physicians and their immediate family members, as well as payments/transfers to those owner/investor physicians, are reportable by the manufacturer/GPO, regardless of whether the physician is also an employee. (Immediate family will be defined as spouse; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.)

CMS is using this rule-making opportunity to address physician-owned distributors (PODs) and other physician-owned intermediary companies (POCs) in the medical device supply chain. These companies, often owned by orthopedists and cardiologists, have been on the CMS radar for several years, since CMS is concerned about the potential for

inappropriate payments, which PODs and POCs present. By requiring these transparency reports, CMS will get those relationships out in the open.

What information will be reported?

Required transparency reports must include the name, business address of the recipient, and, if the recipient is a physician, his or her specialty and National Provider Identifier (NPI). The amount and dates of the payment or other transfer also must be reported. In addition, the report must include a description of the form of payment, whether cash or cash equivalent, in-kind items or services, stock or stock options, or any other form of payment. The nature or purpose of the payment must also be reported in one of 15 categories: consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food and beverage, travel and lodging, education, research, charitable contribution, royalty/license, current or prospective ownership or investment interest, compensation for serving as a faculty member or speaker for medical education program, grant, and other. Payments for speaking are reportable even if the speaking is not in the context of accredited CME or a formal program.

CMS is proposing that payment to a physician include payment to the physician through his or her physician group. Payments provided through a group are to be reported individually under the name of the physician recipient. If a payment is made at a physician's request to another individual or entity, the other individual or entity's name also must be reported to "maximize transparency about the details of the payment or other transfer of value, by allowing end users to discern whether a physician actually received the payment, and if not, where the payment went."¹

Are any payments or ownership interests exempt from reporting?

Payments/transfers below the \$10/\$100 thresholds are exempt from reporting. Also

exempt are ownership or investment interests in a publicly traded security or mutual fund and interests that arise from a retirement plan offered by a manufacturer to the physician or member of his immediate family through employment.

In addition, stock options and convertible securities received as compensation are not reportable until the stock options are exercised or the convertible securities are converted into equity. Transfers of educational materials to benefit patients, short-term loans of medical devices, rebates, discounts, and items provided under warranty also are not reportable.

What do physicians need to prepare for?

The first transparency reports are required by March 31, 2013 and will cover the previous calendar year's payments. HHS will review and compile the information and give the reporting entities a chance to correct it. CMS anticipates that physicians may be interested in reviewing the data reported about them. Therefore, CMS proposes to allow, but not require, physician recipients and owners/investors, to register with CMS to ensure they receive communication about the data submitted and the review processes. If a physician wishes to dispute a transparency report, it will be up to him or her to do that directly with the manufacturer or GPO. CMS will not be actively involved in arbitrating such disputes. There will be a mechanism for reporting to CMS concerning disputes and the resolution of those disputes during the 45-day information review period, prior to public disclosure. On September 30, 2013, and each year thereafter, CMS will make the information available to the public on searchable website.

The CMS website will indicate that the disclosure of a payment does not necessarily indicate that there is a conflict of interest or wrongdoing, but the website will also state that the disclosure does not indicate that the payment was legitimate. Physicians will need to prepare themselves for the scrutiny

and reactions from patients and others that public knowledge of payments and ownership interests may cause.² Furthermore, since the Sunshine Act will provide complete transparency about payments flowing from manufacturers and GPOs to physicians and teaching hospitals, it will make it far easier for the government, the media and the public to identify inappropriate payments when those occur. Thus, the law creates a platform for more vigorous enforcement activity relating to the Federal Anti-Kickback Statute and the Federal False Claims Act.

Sunshine is the best disinfectant

At least that is what legendary US Supreme Court Justice Louis Brandeis once said. That's why CMS hopes that this new regulatory scheme will tend to reduce or eliminate those payments from manufacturers to physicians and teaching hospitals which can introduce conflicts of interest that inappropriately influence research, education, and clinical decision-making. The CMS commentary accompanying the proposed rule notes that some drug and device companies may decide that the costs of reporting outweigh the benefit of having reportable relationships.

References

1. 76 Fed. Reg. 78742, 78746.
2. Wolston M. An MS patient loses trust when she finds out her doctor is paid by drug companies. *Health Aff.* 2011;30:2449-2452.

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