

The Sunshine Act: It's For Real Now

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The Sunshine Act, which became law on March 23, 2010,¹ requires manufacturers of drugs, devices, biologicals and medical supplies to report to the US Department of Health and Human Services (HHS) certain payments and “transfers of value” to physicians and teaching hospitals (“covered recipients”). Payments to residents are not included in the reporting requirement. The Act also requires applicable manufacturers (AMs) and group purchasing organizations (GPOs), including those owned by physicians, to submit reports regarding ownership/investment interests held by physicians or their immediate family members. Final rules implementing the Act were published February 8, 2013.²

When Does It Become Effective?

The rules will be effective April 9, 2013. AMs and GPOs must begin gathering reportable information August 1, 2013. The first reports (covering August-December 2013) are due at HHS March 31, 2014. Reports will be processed, compiled, and placed in a searchable database for public view by September 30, 2014.

How Does My Name Get in the Database?

It's easy. All you need to do is receive, directly or indirectly, a single payment/transfer worth \$10 or more, or cumulative payments/transfers of \$100 or more in a calendar year, and your

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name will appear in the database. Your principal practice address and specialty will appear as well. Both the form (cash, in-kind, stock, etc) and nature of the payment/transfer will be in the database. The dollar amount of ownership or investment interests will be reported.

The nature or purpose of the payment must be described in one of 16 mutually exclusive categories, including 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, and grant.

What if I Speak at a Medical Education Program?

You may or may not end up in the database. Compensation for serving as a faculty member/speaker for an unaccredited/noncertified continuing medical education (CME) program is reportable, as is speaking at an accredited/certified CME program (in 2 separate nature of payment categories—to distinguish between accredited and non-accredited CME).

However, the compensation need not be reported if it fits into the exception created in the final rules. To make the payment nonreportable, all 3 requirements in the exception must be met: (1) the CME program is accredited by the Council for Continuing Medical Education, American Academy of Family Physicians, American Dental Association, American Medical Association, American Osteopathic Association (2) the AM does not pay the speaker directly; and (3) the AM does not select the covered

recipient speaker, nor give the program organizer a list of specific individuals to consider as speakers. Since these requirements are consistent with many professional societies' approach to industry support for CME programs, it is likely that a lot of that support will not be reportable.

Will I Be Listed Just for Taking Part in the Pharma-sponsored Coffee Break at a CME Program?

The final rule creates a special provision for allocating the cost of food and beverages where it is not possible to separately identify the individuals who participated. So, for example, if the drug rep brings a platter of bagels to your office, the value per person (for determining whether reporting is required) is calculated by dividing the cost of those bagels by the total number of participants, including not only the physician-covered recipients in the office, but also individuals who are not covered recipients, such as office staff. If a physician in the group did not actually share in the food offered (eg, because he was out of town that day), he will not be counted in the denominator for that calculation. Also, AMs are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants at a conference or similar large scale event. Even if the total value exceeds the \$100 annual aggregate reporting threshold, those transfers of value are not reportable.

What If I Don't Want to Be in the Database?

Payments/transfers below the \$10/\$100 thresholds are exempt from reporting, and these

numbers will be adjusted for inflation. Further, no reports are required because you have 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 you (or member of your immediate family) through employment. Transfers of product samples (including coupons and vouchers) and educational materials intended to benefit patients, short-term loans of medical devices, educational services to patients, rebates, discounts, and items provided under warranty also are not reportable. Additionally, if you provide consulting or expert witness services to an AM in connection with a legal proceeding (civil, criminal or administrative), it is not reportable.

What Should I Do Now?

Review all of your relationships with AMs and GPOs. Make sure they will pass legal muster in the light of day. You can be sure the Office of the Inspector General and other regulators are

looking forward to mining this database.

If you receive payments/transfers from AMs or GPOs, keep track of them. You can then take advantage of your opportunity during the 45-day review period to make sure the information to be reported about you is accurate. You can review this information using online posting and notifications on CMS's list server, or you may register with CMS to receive notification about the review process. You will be able to login to a secure website to view information that has been reported about you. It is important to do this in a timely way since data corrected after the 45-day period by the AM/GPO will not be changed in the database until the following year. If your dispute on the accuracy of a report is brought to CMS's attention in a timely way, then even if it is not resolved before publication of the reports, CMS will mark the report as disputed. Unfortunately, if you have a dispute with the AM/GPO, it is yours to pursue and CMS will not assist.

It is likely that in the early implementation

of this massive program, there will be many glitches and hiccups. So you should be particularly vigilant starting this August and continuing at least through the publication of the first few annual data dumps.

REFERENCES

1. Katayama AC. Shedding Light on What the Sunshine Act Will Mean for Physicians. *WMJ*. 2012;111(1):39-40.
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Editor's Note: *Wisconsin Medical Society policy ETH-004: The Relationship of the Profession to the Health Product Industry addresses the acceptance of gifts from those who provide health products prescribed by physicians, including the pharmaceutical and device industries. To read the policy, visit <http://bit.ly/Zsldlj>.*

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