

Is the Sunshine Act Worthy of Concern?

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Practice Points

- If you have financial relationships with the pharmaceutical industry, you will need to anticipate the implications of the increased scrutiny that may result from Sunshine Act reporting.
- Do not trust the industry to report accurately; verify reports each year and make corrections as needed.
- If you do not see pharmaceutical representatives or attend industry dinners, do not assume that you will not be reported. You may be indirectly involved in compensation that you were not aware of or you may have been reported in error.

In mid-2013, the federal government launched the Physician Payments Sunshine Act (referred to as the Sunshine Act), yet another new bureaucracy as a component of the Patient Protection and Affordable Care Act. Since August 2013, all manufacturers of drugs, devices, and biological and medical supplies covered by federal health care programs have been required to collect and track all financial relationships with physicians and teaching hospitals and report the information to the Centers for Medicare & Medicaid Services (CMS).¹ Manufacturers must report all financial exchanges, including the type of exchange, the dollar amount, and the reason for the interaction, such as consulting, food, honoraria, travel, education, gifts, grants, direct payments to speakers at educational programs, research, and any ownership or investment interests in the company by physicians and/or their family members.¹ Beginning in September 2014, most of this collected data will be published online by the CMS for all to see.²

What Data Gets Reported

Compensation for conducting clinical trials will be reported but not posted on the CMS Web site until the product receives US Food and Drug Administration

approval or until 4 years after the payment, whichever comes first. Payment for clinical trials involving a new indication for an approved drug will be posted immediately.¹

There are a number of specific exclusions, such as funding of certified and accredited continuing medical education activities and supplying product samples for patient use. All financial relationships with medical students and residents are entirely excluded. Items furnished to your nonphysician employees but not to you also are excluded. For example, if a sales representative brings lunch for your staff and you do not consume any of it, be sure that it is documented correctly so you will not have that particular transaction reported.

Keep Track of What Is Reported

Although you, as a physician, have no reporting responsibilities, you will want to be certain that what is reported about you is accurate, which means keeping your own records of any money, food, or supplies that you receive from pharmaceutical companies and making certain that it is in fact your information, and not someone else's information, that is published.

Start by updating your professional information on file with the CMS. If you have a National Provider Identifier (NPI), verify that the information in the NPI database is up-to-date because manufacturers will use NPI information as a primary means of identifying you in the database. You may want to download the Open Payments Mobile for Physicians app,³ which

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will allow you to collect reportable transactions between you and industry representatives quickly and relatively easily. The app is available for free for a range of mobile devices.

Dates to Remember

Moving forward, all data must be reported annually by manufacturers to the CMS by March 31, so you will need to set aside time in April and May to review what has been reported. If you have many or complex industry relationships, you should probably contact each of the manufacturers in January or February and ask to see their data before it is submitted, then review it again once the CMS gets it to be sure that nothing was changed. Maintaining accurate financial records has always been important, but now it will be even more crucial to effectively dispute any inconsistencies.

You will be allowed to review your consolidated data and seek corrections before it is published, but only after all pharmaceutical companies submit their information to the government. You will have an additional 2 years to pursue corrections after publication, but in the interim, the incorrect data will be posted online.⁴

If you do not see drug representatives, attend industry dinners, or give sponsored talks, do not assume that you will not be on the CMS Web site. Check anyway, as you might be indirectly involved in some compensation that you were not aware of or you may have been reported in error.

Impact of the Sunshine Act

Once the CMS collects and publishes this information, will it have any substantial impact? What will be the likely effects on research, industry-sponsored meetings, meals provided by drug representatives, and other related exchanges? The short answer is that no one knows. Much will depend on how the information is reported and how patients interpret the data that they see, if they take any notice at all. The fellows at Harvard University's Edmond J. Safra Research Laboratory predict "somewhat dim illumination from the Sunshine Act."⁵

Physician payment sunshine laws already are in effect in California, Colorado, Connecticut, Massachusetts, Minnesota, Vermont, and West Virginia, as well as the District of Columbia⁶; Maine repealed its sunshine law in 2011.⁷ According to a 2012 report,⁸ studies in Maine and West Virginia showed no significant changes in prescribing patterns after the laws took effect.⁹

Evidence indicates that physicians have already decreased industry interaction on their own, as approximately one-quarter of all private practices now refuse to see pharmaceutical representatives.¹⁰ Most medical

schools prohibit samples, gifts, and on-site meals, and many prohibit on-site interaction of any kind between pharmaceutical representatives and residents.^{11,12}

The effect of disclosure legislation on physician-patient interactions remains equally unclear. Do patients think less of doctors who accept an occasional industry-sponsored lunch for their employees? Do patients think more of doctors who conduct industry-sponsored clinical research? There is little objective data; however, Rosenthal and Mello¹³ concluded that "disclosure without expert assistance in interpreting these disclosures will have little effect on consumer behavior."¹³

Final Thoughts

Based only on my 33 years of experience, my own prediction is that attorneys, activists, and the occasional reporter will regularly be data mining the CMS Web site, but few patients will bother to seek out the information. Nevertheless, you should prepare now to ensure the accuracy of anything posted about you when the database launches this year.

Pharmaceutical companies face stiff penalties if they do not comply with the Sunshine Act. Failure to report could result in a fine up to \$150,000 annually, and those fines can rise to \$1 million if payment information is intentionally not submitted,¹⁴ which means that all information will undoubtedly be disclosed. If you have any financial relationships with the pharmaceutical industry, you will need to anticipate the implications of the increased scrutiny that may (or may not) result.

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