

Physician Payment Sunshine Act: Implications for School of Medicine Faculty

There is a broad consensus in academic medicine that collaborations between physicians and industry (e.g., drug and medical device manufacturers) are vital to the discovery and development of life-saving drugs, therapies and medical devices. However, there is also a consensus that there must be boundaries and appropriate balance to reduce conflicts of interest that affect teaching and clinical care. As summarized by Korn and Carlat, “Drug and device promotional practices (including free gifts and meals, payments for speaking and other transfers of value) lead to shifts in physicians’ treatment choices and teaching, favoring new and more expensive products over existing ones that are just as effective, cheaper and have longer track records of safety.”¹

The Physician Payment Sunshine Act (Sunshine Act) was enacted in 2010 by the federal government as part of the Patient Protection and Affordable Care Act. The Sunshine Act requires pharmaceutical and medical device companies to report payments and other “transfers of value” made to physicians and teaching hospitals to the Centers for Medicare and Medicaid Services (CMS) for inclusion in a publicly-accessible database. According to the Congressional sponsors of the Sunshine Act, “The process is not designed to stop, chill or call into question beneficial interactions between physicians and industry, but to ensure that they are transparent.”

The Sunshine Act seeks to:

- Promote transparency regarding financial payments from pharmaceutical and medical device companies to physicians;
- Reveal the nature and extent of financial relationships, and;
- Provide information to health care consumers to allow them to make informed decisions.

Undisclosed payments to physicians for promotional speaking were a particular concern and were targeted as a priority by Senator Chuck Grassley and other sponsors of the legislation. Ten states (including Colorado) have similar statutes, requiring public posting of payments that physicians receive from industry.

Implementation

The Final Rule for the Sunshine Act was issued by Department of Health and Human Services on February 8, 2013. All covered industries were required to begin tracking payments to physicians starting on August 1, 2013. In fact, many pharmaceutical companies had been voluntarily tracking and reporting such payments long before the law became effective.

¹ JAMA, 2013

The first annual reports from industry to CMS are due in March 2014 (covering payment data from August 1, 2013 to December 31, 2013). All data are collected on a calendar year cycle and reported by industry to CMS once per year.

Reporting Details and Logistics

Companies began collecting payment data on August 1, 2013. Beginning in 2014, companies will be required to report payment data to CMS, which will then post the data on a website that can be searched by healthcare consumers. The searchable database will be available to the public on September 30, 2014 (in future years, updated data will be available on June 30).

Critical Questions

- **Who is required to report?** The answer is, *all companies that have a physical presence in the United States and manufacture products covered by Medicare, including pharmaceuticals, medical devices and medical supplies*. The obligation to report payments and transfers of value rests entirely with the company that made the payment; **physicians have no reporting obligations**.
- **What data is reported?** All payments or other “transfers of value” worth \$10 or more from a covered manufacturer to a physician or teaching hospital. “Physician” includes doctors of medicine, osteopathy, dentistry, dental surgery, podiatry, optometry and chiropractic medicine. Payments to residents, allied health professionals and non-physician prescribers are excluded from the reporting requirement. Non-physician scientists are also excluded.

The covered payments and “transfers of value” include:

- Consulting fees (or other compensation for consulting, such as dividends, profits or stock options)
- Payments for speaking, including direct payments for speaking at continuing education courses that are not accredited
- Honoraria of all types
- Research-related expenses
- Textbooks and articles
- Gifts, entertainment, food, travel and lodging
- Scholarships and other education-related payments
- Charitable contributions
- Royalties or licensing fees
- Grants

- Facility and (for teaching hospitals), space rental fees.

For non-cash payments (such as food and beverages), manufacturers will report the estimated value of the payment.

- **What is exempt from reporting?** Honoraria for lecturing at certified and accredited CME courses are excluded from the Sunshine Act reporting requirements, so long as the company does not have any role in suggesting or selecting speakers, and so long as the company does not pay the physician directly. Short-term loans of medical devices are excluded, as are buffet meals, snacks and beverages generally available to participants of large-scale professional conferences. Drug and products samples and educational materials that *directly benefit patients* are excluded from reporting under the Sunshine Act. However, textbooks and article reprints are *not* excluded under this provision. Payments and transfers of value worth less than \$10 are also excluded, as are in-kind items used for the provision of charity care.
- **Are payments to third parties reported (and under whose name)?** Payments made by a manufacturer to a third party, on behalf of a physician, *will be reported under the identity of the individual physician who performed the services or who was the intended beneficiary of the payment*. For example, payments to the University of Colorado, to the School of Medicine or to UPI, intended to compensate for consulting or other services performed by a physician, will be reported under the identity of the physician who performed the services. Payments given to another person or to a preferred charity must also be reported.
- **What information will appear on the public website?** The following data will be reported by the manufacturer and subsequently disclosed to the public: Name, business address, state license number and practice specialty of the physician receiving the payment; the date and amount of the payment; the reason for the payment (for example, research, consulting, gift, honoraria, entertainment, travel or speaking honoraria); and any pharmaceutical product, biological or medical device related to the payment.
- **What are the penalties for failure to comply with the Sunshine Act?** CMS may impose a penalty of \$10,000 for each failure to report a payment. “Purposeful failure” to report is subject to a fine of up to \$100,000 per violation. Because of these high penalties, drug and device companies are expected to be inclusive and far-reaching in the payment data they report.
- **Will physicians be notified when payments are reported?** CMS will notify physicians that a manufacturer has reported a payment, if the physician registers with CMS to receive such notification. In June 2014, CMS will provide physicians with access to their personal financial disclosure reports for the prior calendar year.
- **What if the reported data are inaccurate?** Physicians will be able to access their data *prior* to public posting. Physicians can challenge the accuracy of the data through an established dispute resolution process. *Therefore, it is important for physicians to maintain independent records regarding payments from industry.* If a physician disputes the accuracy of data submitted by a manufacturer to

CMS, the agency will have at least 45 days to review the data and work with the manufacturer to resolve the dispute and clarify or eliminate the data. If no resolution is achieved, the data will be publically posted by CMS with a notation that the data are in dispute. Early in 2014, CMS is expected to launch its new portal, where physicians can sign up to receive notices when their individual consolidated data are available for review, and where physicians can contact manufacturers to dispute the accuracy of a report.

Your Responsibilities as a School of Medicine Physician

- First, remember that physicians have no obligation to report payments from manufacturers. Reporting obligations rest solely with the manufacturers.
- Physicians should nonetheless maintain accurate records of payments from industry in case they want to dispute the accuracy of the data being reported about them. The American Medical Association has created a free Smartphone app ([OPEN PAYMENTS Mobile for Physicians](#)) to help physicians track reportable payments.
- Physicians should register with CMS in order to receive advance notification of any payment data reported by a manufacturer to CMS about the physician. Physicians may register with CMS beginning in 2014. [Click here for more information about the physician registration process.](#)

Remember that the Sunshine Act does not replace or supersede other university and state of Colorado reporting requirements. Faculty members must report all payments, ownership interests and other financial ties to the [University of Colorado Denver Conflict of Interest and Commitment Office](#). Physicians and other licensed providers in Colorado must also provide regular disclosures of financial interests to the [Colorado Medical Board](#).

The American Medical Association offers this additional advice: *Physicians should “ensure that all financial and conflict-of-interest disclosures required by [their employer] are current and updated regularly. Review and update these disclosures several times each year. Those entities requiring financial or conflict-of-interest disclosures may compare information posted on the public website.”*

Information about the Sunshine Act and frequently asked questions are being updated frequently by the AMA, CMS, the AAMC and other organizations. For the latest information and access to archived webinars, visit any of the following: <http://ama-assn.org/go/sunshine>; or <http://www.policymed.com/2013/12/physician-payment-sunshine-act-listing-of-policy-and-medicine-resources-for-open-payments.html>.