Implications of the Sunshine Act—Revelations, Loopholes, and Impact
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The Physician Payments Sunshine Act of 2007 was introduced by Senator Chuck Grassley (Republican, Iowa) and ultimately made a part of the Patient Protection and Affordable Care Act, Public Law 111-148, which was passed by the 111th Congress and signed into law by President Obama on March 23, 2010.1 Senator Grassley intended to shine light on companies that made payments to physicians and on the amounts of money that physicians and other providers received from industry; he hoped this would influence more cost-effective practice patterns.2 Public access to the payments was provided so that patients would know about their doctors’ financial relationships with industry. The impact so far seems rather subdued.

The drug and device industry cannot be expected to stop paying physicians because their success depends on selling drugs and devices, and the best industry salespeople are physicians. Otherwise, why would industry pay millions of dollars to have physician give sales pitches instead of their own salespeople who have the same data the physicians use? And why would industry spend millions more dollars to influence its key opinion leaders (KOLs) to convince others to prescribe their drugs and order their devices?

Of course, saying “no” is an option for providers, but “no” was not a common response from ophthalmologists as Chang’s article3 in this issue of Ophthalmology reveals (see page 656). In fact, there were 55,996 separate industry payments to ophthalmologists totaling approximately $11M in the final 5 months of 2013, the first reporting period of the Open Payments Program (OPP), the result of the Sunshine Law. The breakdown of payments is interesting, with approximately $4.6M going for consulting. Food and beverage accounted for some $1.6M, and speaking at nonaccredited educational and other promotional events totaled a bit more than $1.8M. A common scenario is that KOLs give talks that rank and file ophthalmologists attend. Although the KOL receives a consulting fee, listeners receive a free meal. The number of KOLs is a small fraction of the number of rank and file listeners who listen to subtle or direct pitches for industry products. As Chang’s report shows,3 the many listeners receive only one third as much of the industry payouts as the KOLS receive. Trivial as the meals may seem, they matter, because, as study after study shows, physicians don’t believe they are influenced, but believe that their colleagues are.4 Industry uses social psychology to its best advantage to influence physicians.5 Still, the OPP database, difficult as it may be to navigate, provides a level of transparency not been before to shine light on industry payments to physicians and other providers.

In the course of deciding the final rules for industry to use in preparing its OPP reports, the Centers for Medicare & Medicaid Services (CMS) sought public comment. After considering those comments, the CMS released its final rule on Open Payments. The outcome has been that although many payments to physicians have been reported, many other payments were exempted from reporting requirements. Why? It seems that public comment influenced the CMS to create loopholes.

This was surprising because, in a response to public comments relating to a reporting issue, the CMS stated the following:

We believe that not all open payments or other transfers of value will be related to specific drugs, devices, biological, or medical supplies, but they nevertheless represent a financial relationship between an applicable manufacturer and a covered recipient that has the potential to affect medical judgment and must be reported under the requirements in section 1128G of the Act. Additionally, we are concerned that limiting the reporting requirements to payments or other transfers of value related to covered products would create loopholes that would allow entities to avoid reporting of certain payments of other transfers of value.6

Although this comment by the CMS seemingly reflected an understanding of how industry money biases practice decisions, the CMS went on to create a number of official loopholes that contradict its own reasoning.

For example, the CMS’s Final Rule discussed how payments for meals would be reported. The cost of meals provided to practitioner offices would be divided by the number of those who partook of the meal, including staff. If the cost per physician who ate the meal met the $10 reporting threshold, then each practitioner who ate the meal would be listed by name in industry’s report to the CMS. Practitioners in a group practice who opted out of the meal would not be included in the report. All well and good. Yet, the CMS Final Rule exempts payments for meals to large buffets, and physicians a way to take part in them without the transparency that the Sunshine Act aims to provide.

While shining light on payments physicians receive that might influence their practice habits, perhaps of even greater interest is how industry and physicians may be adapting to the Sunshine reporting rules.
A second example of a loophole created by the CMS was exempting reporting requirements of all “indirect” payments to physicians who serve as faculty for “certified” and “accredited” continuing medical education (CME) programs. The rationale provided by the CMS states that this type of CME program “generally includes safeguards designed to reduce industry influence.” Thus, for example, what industry terms an “unrestricted grant” may be awarded to support accredited CME offerings, including paying its faculty and speakers and providing meals for attendees without having to report those gifts under the OPP. As long as money is not given directly to the speaker/faculty member, there is no need to report it. Untold funds, easily adding up to hundreds of thousands or perhaps millions of dollars in unreported gifts, are provided in this way by industry.

Industry is helped when the CMS gives its stamp of approval for industry-funded meals given to large groups of unidentifiable physicians and unreported gifts for industry-funded CME courses with indirect payments. The more detached it appears that industry is from the money and meals it provides to physicians, the less suspecting those physicians are to industry’s motives to bias their clinical judgment.

There is also no reporting requirement for drug samples given to physicians to give to their patients even though it is well known that samples drive up the cost of healthcare without improving it and can place financial burdens on the patients who receive them. When samples of a particular expensive drug are no longer provided, patients have to pay out-of-pocket for the high co-pay or for the full cost of the drug. Discounts or rebates given to physicians as inducements to use an expensive drug are also exempt from reporting. Also noteworthy is the ability of company personnel to provide a “payment or transfer of value” to a physician if it is given “solely in the context of a personal, nonbusiness-related relationship.” Even the U.S. Congress can have a conflict of interest problem with an arrangement like this even when it is reported.

Just how important to industry and to those benefiting from industry’s largesse is the accredited CME exemption? As Figure 1 in Chang’s article shows, of the total of approximately $11M in total industry payments made to ophthalmologists between August 1, 2013, and December 31, 2013, only $7000 was reported for ophthalmologists who served as faculty members or speakers at accredited/certified CME events. Thus, industry unrestricted grants and the faculty who are paid from them are exempted from public disclosure. So much for transparency. The CMS shows a surprising lack of understanding of—or, more likely, turns the other cheek to—the practice implications of industry-supported CME, accredited or not, and no matter how indirect the payments. Industry supports these programs for the reason it supports all of its efforts: to raise shareholder value—in this case by increasing prescriptions for expensive drugs and tests. Although transparency is created by the payments that have been disclosed, there are other important payments that remain hidden. Does Congress accept this? Either way, there is much more to the Open Payments story than the database.

What are the implications of the Sunshine Act? While shining light on payments physicians receive that might influence their practice habits, perhaps of even greater interest is how industry and physicians may be adapting to the Sunshine reporting rules. For example, there are the medical communications companies (MCCs) that receive industry funding to promote the business of drug and device companies. The relationship between industry and MCCs is, in many ways, a subterfuge to give the appearance of an arm’s length interaction. However, common sense alone tells us that MCCs that are not helping a drug or device company’s bottom line will lose favor with the funding company. Loss of favor means loss of funding.

In a recent article, Rothman et al. reported on the grant-making by 13 pharmaceutical companies and 1 medical device company that voluntarily or because of government settlements had posted details of these transactions on their 2010 websites. The authors found that hundreds of millions of dollars are spent on educational and promotional activities by medical communication companies on behalf of drug companies. Online courses are included, some of them free; MCCs collect physicians’ personal data as a part of their participation in many of these online CME offerings and may share these data with third parties. None of the money that industry provides to MCCs is reported under the Sunshine Act. According to Schwartz and Woloshin, some of the money is used on courses for nonphysicians whose participation in CME-accredited activities more than tripled between 2003 and 2012—from 3 million to 10 million attendees. In a similar timeframe, physician participation in CME-accredited programs increased at a less rapid rate, from 6 million to 14 million attendees. Because prescribing practices are influenced by many nonphysician providers as well as by house officers, the lack of a means to report the industry money received by these groups leaves a significant hole in the Open Payments database and further compromises full transparency. Of note, although MCCs make up just 7% of accredited CME organizations, they produce offerings that account for 43% of nonphysician and 30% of physician CME participation.

Industry advisors are suggesting that, as a result of the Sunshine Act, KOLs will back away from industry to protect their reputations and that industry should move toward using community thought leaders instead to promote their drugs and devices as part of a speaker bureau. In another article reporting on advice given by Alliance Life Sciences Consulting Group, the point was made that some KOL activities on behalf of industry are being restricted by their university’s policies. In turn, the report goes on to say that companies need to move to social media to promote their products directly to providers and that products need to show value to improve healthcare outcomes and reduce costs.

What will be the impact of transparency on physician behavior and on healthcare quality and cost? Rosenthal and Mello suggest that left to the public, nothing much will happen because evidence exists that the public does not use existing health-related databases to help their healthcare decisions. However, these authors propose that health insurers and accountable care organizations have the means and financial incentive to reduce the use of costly drugs and tests. Consumer groups could do the same while providing easier ways for patients to access payment data on their own.
providers. These groups could scrutinize the OPP database and, armed with industry payment information and the support of patients, prod physicians into changing their practice behavior in positive ways.

The effect that the Open Payments database will have on controlling healthcare costs remains to be seen. It provides a plethora of data, but exempts some critical payment categories and important prescriber groups, including physicians-in-training and nonphysician providers. Consequently, we know much, but probably not enough, about how payments are distributed and their potential impact. The database is cumbersome and even daunting for a patient to navigate, even with available filtered searches. One can hope that the next release will be more complete, provide additional data for activities now not reported, and be easier to use.

References