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## Who Gets Burned by the Sunshine Act?

**New laws shed a spotlight on your paid connections to industry, making them more public than ever.**

**By Samantha Stahl, Assistant Editor**

It wasn't all that long ago that receiving an umbrella decked out in an industry logo or having a meal at an upscale steak house with a pharma rep wasn't something anyone thought twice about. Unfortunately, greater scrutiny of the physician-industry relationship — some warranted, some not — prompted calls for a formal regulation of these dynamics. When pharma sales reps got too comfortable with the idea of promoting off-label uses of certain products, worrywarts had a new argument for greater industry transparency.

Thus was born the Physician Payments Sunshine Act, a little-known part of the federal healthcare reform law. The Act requires companies to record any physician payments that are worth more than \$10 and report them to the government, where they will be made public.

The honorarium for a talk you gave at a company's exhibition booth? That gets reported. The light lunch a company paid for during the last meeting you attended? That gets reported, too. Research grants, consulting fees, travel expenses for conferences, stock options and gifts all get reported to the department of Health and Human Services.

The rules governing this process are still in flux — and indeed already behind schedule. CMS missed its original deadline of October 1, 2011, the date by which it had been required to issue a Proposed Rule on implementation. That eventually appeared on December 14, 2011.

The record-keeping of physician payments was initially meant to begin on January 1, 2012, but after CMS's delay, the 2012 start date has yet to be determined. Reports for 2012 activity are due to HHS by March 31, 2013. These reports will then be made publicly available on September 30, 2013 on a searchable database. Each year thereafter, reports will be due on the 90th day of the next year.

Will the new payment reporting requirements ultimately end up being no big deal? Or is this law simply a harbinger of further oversight to come?

## Too Close For Comfort

Historically, the ophthalmology profession hasn't had the types of industry-related scandals that other medical specialties, like spine surgery, cardiology and orthopedics, have run into. Last summer, for example, the Maryland Board of Physicians revoked the medical license of a cardiologist after it was revealed that he was falsifying patient records to justify expensive — and unneeded — cardiac stent procedures at the St. Joseph Medical Center outside of Baltimore.

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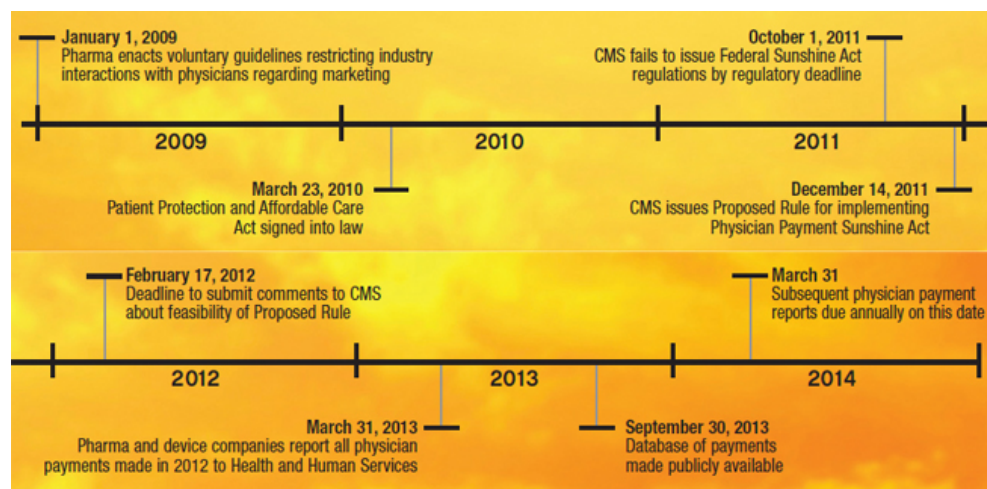
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The case represents the significant pressure a medical practitioner can feel to remain loyal to companies that are willing to pamper the doctors who use their products most. The cardiologist, for example, received millions of dollars in salary and other benefits for his numerous (and ethically questionable) stent procedures — including a lavish \$2000 pig roast the maker of the cardiac stents threw at his house two days after the company found out that the surgeon had inserted 30 of the stents in one day in August 2008.

It's just this kind of coziness that the Physician Payments Sunshine Act is all about.

"There are significant issues if industry can influence physician clinical decision-making to the detriment of the cost and quality of care. Clinical decisions should not be influenced by industry," says William Rich, MD, medical director of health policy for the AAO. "The public is paying for more and more of their care, so they want a side-by-side comparison of these doctor-industry relationships." In an age where patients can research almost everything about their medical problems, prescription side effects and physicians' education history online, it's almost surprising that this kind of database wasn't created earlier.



Transparency is the oft-overused buzzword here. With potentially dramatic changes being made to the entire healthcare system, no one wants to feel duped. No patient should worry that the only reason his doctor recommended a certain prescription was because the manufacturer sponsored his last trip to Hawaii. The more information that is publicly accessible, the more secure the public feels.

Dr. Rich says that there are few in the ophthalmic community who have argued against the disclosures. "This is a good form of transparency. People who are doing the right thing have nothing to worry about."

### Don't Sweat the Small Stuff?

Few will argue that a big-time consulting contract is going to have an effect on prescribing habits on some level. "We're human. Six figures *will* influence our enthusiasm," jokes Larry Patterson, MD, of Crossville, Tenn.

But the Sunshine Act isn't just concerned with the huge stuff — Congress wants to know about the slices of pizza and office supplies, too. Is this law suggesting that a highly educated physician can't decide for himself if a company is trying to bribe him into using their product? Well, turns out it doesn't matter if you're one of the highest-paid surgeons in the country — no one is immune to scrutiny over a free lunch. A study published in the *Journal of the American Medical Association* in 2000 revealed that even small gifts influence prescribing tendencies.<sup>1</sup> After all, would the pharmaceutical companies bother buying you lunch and handing you a branded pen if they didn't have research to prove that the tactics were working?

Probably not.

## Protection, or Overregulation?

"Pharma companies provide great value through the research funding they provide, but people have gotten into trouble in the past when the marketing side of industry has tried to influence the research that is done, or the way results are presented," says Bill Sacks, the vice president of Health Care Compliance Strategies, a company that specializes in conflict of interest management for hospitals, large academic medical centers and institutional providers.

He believes that complying with the new rule will be important to maintaining positive public relations. Big research universities that obtain a lot of funding from industry should be prepared to do some explaining.

Mr. Sacks, whose software allows organizations to track front-end disclosures for easier reporting, says that it will be important for institutions to have a spokesperson on hand who understands the issue and can speak articulately if the public requests a clarification about how and why payments were made to physicians. "People need to understand what the pharma companies will be required to report and be able to discuss that intelligently," says Mr. Sacks. "There are usually perfectly good explanations for the payments," he notes. Because some MDs refuse to attend company-sponsored events out of fear of having a reportable relationship with the company, there has been a trend towards industry giving money to institutions, he explains.

"There is an exorable march to transparency — some are going kicking and screaming, others are embracing it. I think those that embrace it are going to be well received by the public," he says. Mr. Sacks predicts that for doctors, the disclosures may actually be a good thing, a way of increasing communication and trust between doctor and patient.

And there are plenty of physicians who agree with him that, in a way, the disclosures act as a permissible form of bragging rights. "I would prefer that my personal financial information not be disclosed; however, I don't see it as a major problem," says Johnny Gayton, MD, of Warner Robins, Ga. "It confirms to patients that industry values my knowledge and opinions. I think it gives me increased credibility."

He says that several years ago, when the *Atlanta Journal-Constitution* printed an article highlighting him as the highest-volume surgeon in Georgia, the exposure helped bring more patients to his practice who wanted to come in to someone who was experienced. He sees public payment disclosures having a similar effect. "I'm not afraid of 'letting the sunshine in' and sharing the information with my friends," Dr. Gayton says.

Not everyone is enthusiastic about the ruling, though. Paul Koch, MD, of Warwick, RI, says that up until a few years ago, he was always happy to give talks for sponsors. As rules have changed, however, he finds himself turning opportunities down. When he was asked to give a booth talk at ASCRS last year and the company insisted that he sign a one-year consulting agreement — just for a short, single talk — he walked away from the contract and \$500 stipend. "I don't want to have to declare that I consult for someone when I really don't. It's very discouraging as a teacher to have to do these things, so my response is just to decline," he says.

These days, it's nearly impossible to find an unbiased opinion on new products, since almost every talk and article source is given by someone with a relationship to a company. "It's very hard to separate personal message from corporate hype. So in that sense, the Sunshine Act is going to be very positive in knowing where someone is coming from when they give a talk," says Dr. Koch. But he fears the trend towards overregulation may hinder the educational value of meetings. "Company lawyers have demanded to vet everything. It's been really awful to go to meetings and have the speaker only allowed to say things they've been instructed to say."

Retina specialist Peter Kaiser, MD, of the Cleveland Clinic, isn't worried about the negative consequences from the Sunshine Act in ophthalmology, saying the money from companies plays very little part in clinical decisions, especially in comparison to specialties like psychiatry, where expensive drugs are often used off-label with little supporting data. "The act will have minimal impact for our patients, but the idea behind the law is good," Dr. Kaiser says. "It is important to know what your doctor may be receiving from the companies that make the drugs he is prescribing."

Dr. Kaiser, whose relationship with industry has always been in consulting roles with early- and late-stage companies to refine products and design trials, says he'll continue to consult irrespective of the Sunshine Act. "I have never been a member of a speakers bureau, or had a company pay my way to meetings or pay to use their products. That won't change."

## How Will Industry Respond?

For each physician payment that goes unreported by industry, the manufacturer incurs a monetary payment to the government ranging from \$1,000 to \$10,000 — and that's just if it was an accident. If a manufacturer knowingly withholds information, it faces a \$100,000 penalty. For a company with a large staff of physician consultants, those bills could add up.

As sales reps have fewer opportunities to buy into doctors' good sides, will the nature of pharmaceutical and device sales change? Will paid relationships with physicians fade away? Not likely, according to Julie Masow, the director of media relations and issues management for Novartis.

She notes just how critical interactions between healthcare companies and healthcare professionals are developing improvements for patient care and fostering appropriate use of medicines and devices. "When engaging healthcare professionals to provide services, we evaluate healthcare professionals' credentials, experience, commitment to patient interests and demonstrated abilities with respect to the work for which they are being appropriately compensated," she says. "We believe that disclosing payments related to interactions with healthcare professionals helps foster trust and supports our commitment to ethical behavior."

So just how hard will it be for industry to take on the new requirements? Tim Buckley, a marketing VP at Iridex, references the 2002 Sarbanes-Oxley Act imposed on publicly traded companies in the US. He predicts that public medical companies will likely have an easier time adopting the new Sunshine Act rules, since "documenting processes and reporting are already a part of the companies' DNA."

"Interactions between physicians and industry are a fundamental part of identifying the needs within the market," says Mr. Buckley. He recommends that asking industry for a simple emailed agenda for all meetings will help document the business intent. "Ophthalmology is a wonderfully tight community, and I am confident we will all look back and understand the long-term positives gained through the near-term negatives."

While it's clear on both sides that industry-physician relationships are crucial to keep medical breakthroughs evolving, the community can expect some changes. "If you have a relationship with industry related to design of a device or pharmaceutical, then it is appropriate to be compensated for your expertise. But if someone's paying you money to market, that's a different issue," says Dr. Rich. A growing trend in industry is to pay physicians to sit-in on company panels as "advisors," a job that he sees influencing the doctors' decisions in device selection. "These marginal consulting contracts to help with 'strategic planning' for a nice sum of money — I think those are going to go away."

On the other hand, David Parke, MD, executive vice president and CEO of the AAO, doesn't believe that the Sunshine Act will engender fundamental change. "Industry and the physician community have been moving towards greater transparency anyway in order to

support an atmosphere of trust between patients and physicians,” he says. “Leaders in the ophthalmic drug and device industry recognize that trust is a critical element and that concealed relationships never stay concealed.” He also emphasizes that not all regulations for the act have been released at this point by CMS — likely because CMS is realizing just how complicated it will be to track every single \$10 payment. CMS will accept comments on the recently-issued Proposed Rule until February 17, 2012. While the details of the rules will become clearer in coming months, just remember that the next time you have dinner on the company dime, anyone can know. **OM**

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