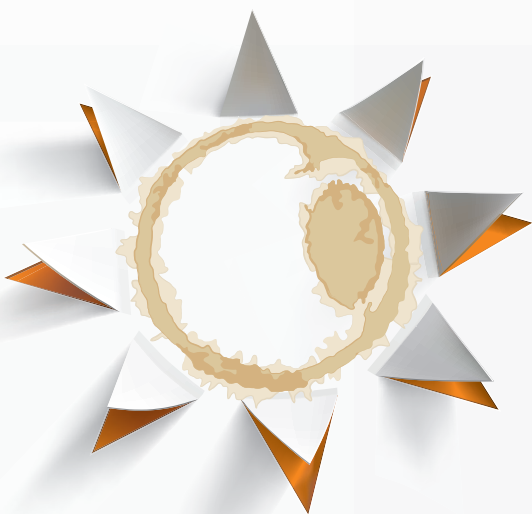


# SUNSHINE



## ON MY SHOULDERS

Drug and device companies are scrambling to meet federal disclosure requirements. Besides forcing industry to amass a torrent of new data, the Sunshine Act is also expected to wreak havoc on pharma-physician relations.

**Joe Dysart** on the consequences of transparency

**P**harma is smarting from the consequences of Obamacare's Sunshine Act, which forces drug and device makers to report virtually all the gifts they give to docs—no matter how negligible.

A cottage industry has sprung up featuring the Big Data software programs pharma will need to comply with the law. And more than a few pharma firms are eyeing the coming year with trepidation, as they await blowback from many doctors who only have a hazy idea of how deeply the Sunshine Act will penetrate their everyday lives.

"There are approximately 3,000 manufacturers of drugs and devices providing valuable education and resources to physicians that enhance patient care," says Michaeline Daboul, CEO of MMIS, a Big Data management company. "Increasing transparency of the relationship between industry and our healthcare providers will undoubtedly encourage scrutiny by the public, physician peers and their institutions."

Perceived by many docs as "something about reporting gifts and free educational texts," the Sunshine Act is actually designed to expose—and make public on a freely available website—every conceivable financial exchange that transpires between doctors, pharma and medical device makers.

Exchanges of cash, cash equivalents, stock, stock options, dividend interest or any other type of ownership interest or other payments must be reported by pharma and medical device makers to the federal government, according to Molly Cooke, MD, president of the American College of Physicians (ACP). That includes consulting fees, honoraria, speaking fees, royalties, gifts, entertainment,

grants, education (but not CME), educational materials and license fees, she says.

The first reports—due to the Centers for Medicare and Medicaid Services by March 31, 2014, for the tracking period of August 1 to December 31, 2013—have pharma companies scrambling, which is fine and dandy with the federal government.

"Disclosure brings about accountability, and accountability will strengthen the credibility of medical research, the marketing of ideas and, ultimately, the practice of medicine," says US Senator Charles Grassley (R-IA), a co-author of the law.

Besides forcing the industry to route a torrent of new data through its computer systems, the Sunshine Act is also expected to wreak havoc on pharma/physician relationships, as inevitable inaccuracies pop up in pharma Sunshine reports to the Centers for Medicare and Medicaid Services (CMS).

Indeed, according to a February 2013 survey released by MMIS, 21% of physicians surveyed said they would sever their relationship with a manufacturer that reported inaccurate information about them under the Sunshine Act. Another 43% of docs asserted that such public mistakes would negatively impact their relationships with such manufacturers.

MMIS's survey also revealed that the risk of inaccuracies in that reporting is great, given that 54% of physicians surveyed said they had received samples from manufacturers, and 57% had received food or beverages. Another 48% of docs surveyed said they had participated in a medical industry sponsored program—also report-

able. Plus, 11% had participated in speaker bureau programs and 10% had participated in advisory board programs. Another 2% said they had received free tickets to entertainment and similar gifts.

Overall, 63% of physicians surveyed expressed deep concern that a record of payments and gifts under the Sunshine Act will be available in a publicly searchable database—complete with doctors’ names.

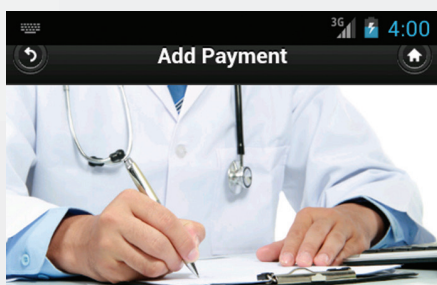
Additional ill will is also anticipated by pharma once more doctors begin realizing that the Sunshine Act will reach into transactions once considered everyday, innocuous and beyond reproach. Forty-five percent of healthcare providers recently surveyed by QPharma, for example, did not know that pharma will be reporting speaker fees—even if the docs ask that those fees be donated to charity.

And 62% of doctors in QPharma’s survey were unaware that samples would be reported. Another 56% said they did not know the FDA now has a record of any samples they’ve signed for from pharma reps.

Even doctors somewhat familiar with the Sunshine Act had their limits. Of those surveyed, 41% knew that gifts \$10-or-greater were reportable, for example. But that group did not realize that a string of less expensive gifts—say, a few cups of coffee over the course of a year—is reportable if their aggregate value exceeds \$100.

Fortunately, the American Medical Association (AMA) is attempting to head off anticipated misunderstandings with a web toolkit designed to quickly bring its members up-to-speed. The kit includes a free webinar on the Sunshine Act, FAQ, important dates to remember and a primer on how to challenge incorrect reports.

“We urge physicians to ask industry representatives with whom they interact to provide an opportunity to review and, if necessary, correct all information they will report before it is submitted to the government,” says AMA President Ardis Hoven, MD.



Fill out the form below to add a new payment:

Select Vendor:

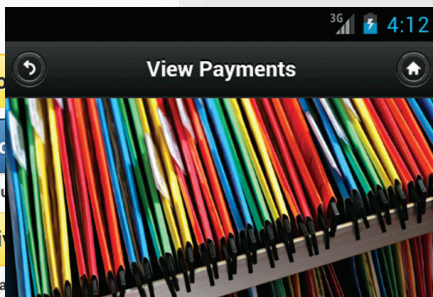
- John Doe - Drug Co
- Create Vendor

Form of Payment or Transfer of Value:

- Cash or cash equivalent
- Food and Beverage

Nature of Payment or Transfer of Value:

Associated Drug/Biological/Device/



A list of your previous payments is below.

Food and Beverage	Jane Doe-7/1/2013	\$35.00
Entertainment	Jane Doe-7/1/2013	\$100.00

Clear All Payments

CMS is attempting to keep things clear by offering a mobile app for doctors to track gifts and similar items from manufacturers, and another manufacturers can use for the same purpose (pictured). “These two apps are an innovation option for doctors and industry to accurately and securely track their financial ties and other transfers of values,” says CMS Program Integrity Director Peter Budettiz, MD.

While handy as private trackers, the apps do not transmit data to CMS. Instead, they’re intended as aids that pharma and doctors can use to ultimately comply with the new law, and verify data accuracy. Both apps are available for download at the Google Play app store and the iOS Apple app store using keyphrase, “Open Payments.”

Infuse Medical, an applications development agency, also offers a tracking app for manufacturers (iPad compatible only), which is free to try out through January 2014. “Pharma reps are already overburdened with massive amounts of information to collect and report,” says Jordan Erickson, president of Infuse Medical. “Our Sunshine Act Compliance mobile application fits right in with the way they are already detailing physicians.”

Not surprisingly, more than a few doctors’ organizations have a problem with the Sunshine Act. The AMA, for example, along with a slew of co-signers, released a letter to Health and Human Services requesting that medical textbooks and journal reprints be excluded from Sunshine Act reporting.

But while many within the pharma and HCP communities are eyeing the Sunshine Act with disdain, Dr. Cooke’s group—the ACP—says it has no problem with the new law. “We see the Sunshine Act as part of an overall shift in medical treatment that makes the patient central to that treatment—rather than an afterthought,” Dr. Cooke says. “After all, no one is more invested in the patient’s health than the patient and the patient’s family.”

Dr. Cooke is quick to add, though, that while well-intended, the drive behind the Sunshine Act to make every conceivable pharma-doctor transaction public is more a concern of lawmakers inside the Washington beltway than a pressing need of the everyday patient.

“As an internist, I’m not seeing this as a top-ten issue among the patients I’m treating,” says Dr. Cooke, an intern at University Hospital, University of San Francisco. “The fact that doctors may be receiving free educational textbooks from a drugmaker just doesn’t bother them.

“As for free weekend trips to Laguna Nigel—sure, those don’t pass the smell test. But that kind of thing doesn’t go on anymore.” ■



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