Stepping into the sunshine

Is the imminent release of the database of industry's 'gifts' to doctors cause for concern or celebration? Charles Schmidt investigates.

A long-awaited database of drug company financial interactions with physicians and hospitals is about to see the light of day. This lesser-known addition to the Affordable Care Act (ACA), the Open Payments Program (OPP; formerly the Sunshine Act) obligates drug and medical device companies to deposit into a public and searchable database all financial transactions worth at least $10—including everything from meals and small gifts, to long-term support for clinical trials, to the ownership and stock holdings of physicians and their family members. That information, along with the names of physicians specified as recipients in the transactions, will be made available by the Baltimore-based US Center for Medicare and Medicaid services (CMS) on a website that is set to launch on September 30.

More than six years in the making, the OPP will ideally limit conflicts of interest in biomedical research and prescribing practices. But many worry that without enough context explaining how industry money is used, the OPP could fuel misperceptions about what companies do to promote medical advances. Those concerns were raised in a letter signed by over 20 medical societies and organizations that was delivered to CMS on July 28. The letter pointed out that physician payments under Medicare Part B had been released without context earlier in the year, leading to what the authors claimed was confusion and misinterpretation. The groups urged CMS to provide contextual information when they post the OPP data later this month. "No one favors clandestine deals made on the basis of external remuneration rather than what's best for patients," says Robert Harbaugh, president of the American Association of Neurological Surgeons, which is one of the groups that signed the letter. "But it's important that this information is reported and interpreted accurately."

Curtailing industry abuses

The OPP was motivated in part by evidence showing that industry support can skew research in favor of company products. In a 2004 study published in the *Canadian Medical Association Journal*, investigators reviewed over 300 randomized clinical trials of which 122 were authored by scientists who declared industry funding. The industry-supported trials were more likely to report pro-industry results than trials authored by scientists who declared other funding sources, the investigators found[1].

Charles Rosen, a professor of orthopedic surgery at the University of California, Irvine, says, "so much of what comes out of medical research is written by people with a vested interest in a product succeeding, and not by unbiased independent authors." To illustrate, Rosen cites a clinical trial in his own area sponsored by Johnson & Johnson, of New Brunswick, New Jersey, which focused on the company's artificial disc for treating back pain. Though the trial failed to include pain relief or improved range of motion as success measures, it was part of the data package used to support approval of the device for marketing. Shortly after commercial release, reports started appearing that patients were experiencing slipping of the disc in their spines; ultimately several hundred patients suffered the side effect and many had to subsequently have the disc surgically removed. The product has now been taken off the market.

Galvanized by that incident, Rosen went on to co-found the Association for Medical Ethics (AME), in Orange, California, which requires that its members—all of them clinicians—publicly disclose payments from manufacturers. At the same time, other instances of malfeasance were provoking calls for transparency into industry's financial relationships with physicians and hospitals. Among them was the case of Scott Rueben, an anesthesiologist from Springfield, Massachusetts, who was jailed after falsifying published data that was favorable to Pfizer of New York and other companies that supported his work, and another instance involving three Harvard psychiatrists who reported to the university only a small fraction of the more than $1 million they had each received from various company relationships[2,3].

To avert more conflicts of interest, states, universities, hospitals and research journals have since imposed or beefed up their disclosure requirements. Growing numbers of voluntary programs are also emerging, both at the level of individual companies, and through professional organizations, such as the AME, the Washington, DC–based Pharmaceutical Research Manufacturers of America (PhRMA) and others.

But according to Anita Griner, the deputy director of the Data Sharing and Partnership Group at the CMS, these disparate efforts lack consistency. "The disclosure and transparency system we have now in the United States is piecemeal and incomplete," she says. As the first transparency program to impose consistent requirements nationwide, the OPP will "streamline reporting burdens on industry," she says, and "make it easier for individuals to see all the information available in one place."

The nuts and bolts

The OPP applies to two types of entities. So-called 'applicable manufacturers' include companies that make drugs, devices, biologics

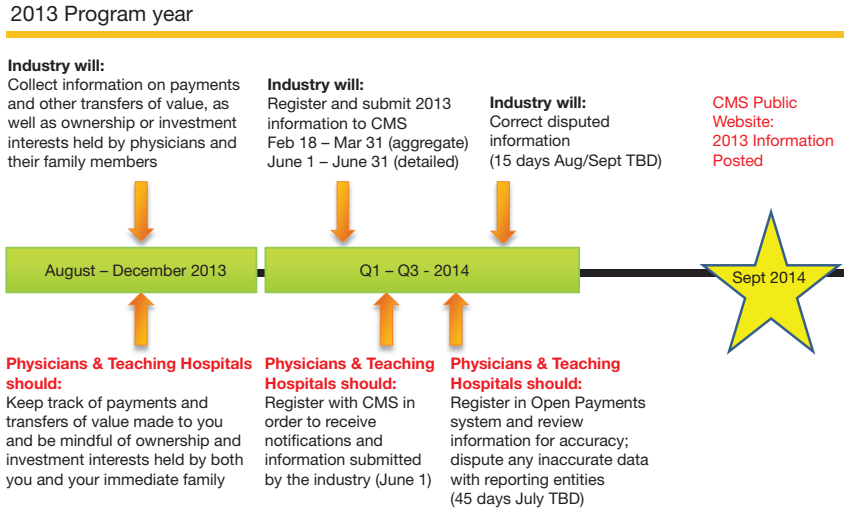

Figure 1 Timeline for the roll out of the OPP. Source: CMS

Table 1 Two types of manufacturer required to make disclosures to OPP[a]

	Applicable type 1 manufacturer	Applicable type 2 manufacturer
Activities	Engages in the production, preparation, propagation, compounding or conversion of a drug, device, biological or medical supply reimbursed by Medicare, Medicaid or Children's Health Insurance Program. This includes distributors or wholesalers that hold title to a covered drug, device, biological or medical supply.	Not only under common ownership with type 1 applicable manufacturers, but also provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply
Examples	Millennium Pharmaceuticals, Johnson & Johnson	

[a]Both types of companies must be based within the US or conduct activities within the US (includes any territory, possession or commonwealth of the US. In addition, their products must be reimbursed by Medicare, Medicaid or Children's Health Insurance Program. For drugs and biologicals, these products require a prescription (or doctor's authorization); for devices and medical supplies, the products require premarket approval or premarket identification by the FDA.

or medical supplies subject to reimbursement under Medicaid, Medicare and other US federal programs. These companies must either have facilities in the United States or sell products made overseas to US-based consumers. The OPP also captures companies that sell commercial products that they license but don't actually produce themselves. Companies that have yet to put a reimbursable product on the market are exempt from OPP reporting (**Table 1**).

The second entity, dubbed 'covered recipients' by the OPP, includes physicians and teaching hospitals on the receiving end of industry's financial transactions. The OPP's reporting requirement falls squarely on industry—covered recipients merely have to register with the OPP secure system so they can track and review the transactions that companies report for accuracy.

The OPP formally kicked off during the summer of 2013, when applicable manufacturers were required to begin recording financial transactions over a five-month period lasting from August through the following December (**Fig. 1**). Those companies then spent the first half of this year reporting the transactions to CMS.

Meanwhile, CMS advised covered recipients to prepare for a 45-day "review and dispute process" that began on July 17 and wrapped up on August 27, 2014. According to Griner, that process allows recipients to flag what they believe are errors in industry reporting. CMS alerts manufacturers of a pending dispute, and what follows is a remediation period during which the two parties should reach an agreement. If they can't agree within the allotted time (to which an additional 15-days can be added if necessary), Griner explains, then the data will be posted on the OPP website, but marked as disputed. Any manufacturer that violates the OPP reporting requirement faces the potential for hefty penalties capped at $1 million per year.

The larger pharmas have so far submitted voluminous amounts of data. Pfizer, for instance, submitted 7.4 million data points on 221,000 transactions. Dina Brachman, public affairs advisor with Pfizer, says none of the companies she's aware of had an easy time uploading the information. Pfizer's entire submission was hung up for hours by just 18 transactions that "miraculously went through while we were on the CMS help line," she says. Brachman says that Pfizer was already well positioned for the OPP, given that the company had been reporting physician payments voluntarily since 2009. "We're experienced in this space," she says. "But we weren't reporting with the kind [of] detail that the new law requires, so we still needed to devote considerable resources to get this accomplished."

Smaller biotech companies have found the data submission effort more burdensome. Tom Knapp, executive vice president with Sucampo, a Bethesda, Maryland–based maker of drugs for gastrointestinal and ophthalmology indications, with roughly $150 million in annual sales, says the OPP's "all-encompassing reporting requirements detract from what we need to do to meet patient needs." He adds, "We applaud the goal of transparency, but we hope CMS can tailor its regime to accommodate smaller companies like ours."

Recipients have also reportedly been challenged in their efforts to log on to the system, and in August, CMS reported that the Review and Dispute system had been temporarily taken offline after it was found that at least one manufacturer had erroneously combined payments associated with different doctors with the same name. CMS officials said they believed the problem was limited to a small number of doctors. "We do not want physicians to see data which does not belong to them, so we are temporarily suspending Open Payments registration…and working with the responsible companies to make them aware of the issue and correct the root data," one CMA official wrote in an e-mail.

Worries over context

By far the biggest concern raised about the OPP's data is how they will be reported to and interpreted by the public. Penn State's Harbaugh explains the dilemma: Harbaugh is principal investigator on a $50,000 industry grant—now in its sixth year—that supports research in his department, as well as educational collaborations with neuroscientists in China. And he worries that if he's cited as principal investigator on the OPP database, this contextual information won't be conveyed to the public, which will see only his name as the grant's personal recipient.

But even with context, the data can be open to different interpretations. In 2012, Yoav Golan, an infectious disease specialist at Tufts Medical Center, in Boston, received $12,050 from Merck. According to an article that appeared in *Forbes,* that money went directly to Tufts as payment for administrative services on a clinical trial that Golan was leading as principal investigator—not to Golan directly[4]. Still, *ProPublica* and *The Boston Globe* erroneously singled Golan out as the payment's recipient in an article about research conflicts of interest[5] (**Box 1**).

Latarsha Stewart, director, legal/compliance with Millennium Biopharmaceuticals, of Cambridge, Massachusetts, agrees that this is a potential problem. Like other companies subject to the OPP, Millennium has to aggregate the payments it makes to principal investigators. Stewart says it's unclear how these funds will be displayed and characterized on the website. Because the aggregated funds represent payments in their entirety over a given reporting period, principal investigators could be viewed simply as having "received a ton of money," she says.

Christopher Clark, who directs the Office for Interactions with Industry at Massachusetts General Hospital (MGH) in Boston, adds that it's not unusual for the public to attach negative baggage to industry funding. Physicians linked to large transactions risk being portrayed by the press as tainted, he says, and this has led to a pervasive sense of wariness among MGH physician-researchers toward the OPP. "They'll tell me, 'I don't want my name showing up on some list,'" Clark says. CMS has tried to address the issue by incorporating a "context field" into the OPP system, where manufacturers can explain what the transactions paid for. The context field is limited to 500 characters (sources debate if that's enough). But because CMS won't release mock-ups of the website before its September 30 release date, it's unclear how this contextual information will be conveyed to the public. CMS representatives responding on e-mail would state only that the website would

display "the nature of payment, amount of the payment or transfer of value, the date of the transaction as well as other data points."

A crystal ball in Massachusetts

The disclosure experience in Massachusetts, meanwhile, provides a glimpse of what could play out nationally with the OPP. Launched in 2009, the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct (http://www.mass.gov/dph/pharmamed) requires companies to disclose all payments of at least $50 to covered recipients, defined as any person or organization in a position to prescribe or decide which drugs or devices will be made available for treatment or covered by insurance. That information is then aggregated and posted on a public website that lists the top 20 manufacturers with the largest payouts, in addition to the top 50 physicians and hospitals with the largest share of industry transactions. The most recent data are for 2012, and they break recipient income into four categories: food, education/training, other and a comprehensive category described only as "bona fide services." The physician who ranked number 2 on the list received a total of $590,508 from seven different companies, of which $538,000 was for bona fide services that weren't defined or described in any way. Officials with the Massachusetts Department of Health and Human Services (DHS, located in Boston) declined to be interviewed for this story. But a DHS press official e-mailed a comprehensive definition for the term, indicating that bona fide services could include participation in a scientific advisory board or continuing medical education, for instance. The qualifying features are that the services must fill a legitimate need identified in advance, based on "fair market value."

A source that did not want to go on record explains that the term "bona-fide service" has its roots in anti-kickback legislation. According to the source, "Companies can be prosecuted if the payments they make to doctors are determined to be bribes. But a defense under anti-kickback rules would be that if a payment is fair-market compensation for a bona fide service, then it is not a bribe. The problem is that the definition is geared more for healthcare lawyers than for members of the general public."

Underscoring the issue is that the press often describes all payments made by companies to covered recipients in a somewhat disparaging way as "gifts." Eric Campbell, a sociologist at Harvard Medical School in Boston, who says that "no industry has proven itself more willing to lie in public than the drug industry," says that it would take a "three-hour conversation" to define what's meant by a "gift." Still, in the absence of clear definitions, the media may not distinguish between gifts and bona fide services. "Media headlines tend to blindly refer to educational grants or services from industry as gifts, and that's discouraging," laments Millennium's Stewart.

To wit: after the Massachusetts DHS posted its 2012 data, the *Boston Business Journal* ran a headline claiming that "Mass. Doctors are getting fewer gifts from drug and device companies"[6]. According to that story, the top 20 companies in spending had given gifts totaling $27.1 million in 2012 compared with $38.3 million in 2010. The reporter quoted disclosure advocates saying the decline "probably reflects hospitals cracking down on conflicts of interest." But MGH's Clark emphasizes that the payments weren't gifts, but rather, "industry support for fellowships and institutional undertakings." He adds, "That gets to the real issue of how these data are interpreted by the media and it reflects a pervasive view that industry relationships are inherently bad."

Interestingly, the same reporter—after speaking with Clark—performed an about-face with a new story suggesting that "millions of dollars spent on doctor training" had disappeared on account of the Massachusetts disclosure law[7]. That loss, the reporter concluded, was a warning call of what might happen nationally with the OPP's public rollout in September.

Potential outcomes debated

Experts have varying opinions on what the OPP can accomplish. Campbell suggests that it probably "won't change what industry gives doctors," but he offers that it could deter doctors from prescribing brand name products instead of cheaper generics. Rosen adds that more disclosure could dissuade companies from trying to ram poor quality drugs and devices—he cites Johnson & Johnson's artificial disc as a specific example—through the regulatory approval process. "More transparency will result in better products, better treatments, lower costs and better healthcare decision making," he says. "We're looking for industry research that isn't covered up by a veil

Box 1 Dollars for Docs

The investigative journalism outfit *ProPublica* of New York is also in the medical disclosure game with its Dollars for Docs website (http://projects.propublica.org/docdollars/), which launched in 2010. Whereas the OPP's content draws from every drug and medical device company with an approved product sold in the US, Dollars for Docs limits its content to disclosures made by just 15 companies since 2009. The companies were all previously accused of improper marketing, or of paying kickbacks to doctors, and the disclosures are required under corporate integrity agreements negotiated by the US Department of Health and Human Services.

ProPublica mines those disclosures to generate the website, which contains roughly 2.1 million records (representing $2.5 billion in payments) as of its most recent update in March, 2014. Users can search for specific doctors, companies or hospitals by state, and the payments are broken out as meals, speaking and consulting fees. According to Charles Ornstein, a senior reporter with ProPublica, Dollars for Docs supplies information that consumers can use when choosing a healthcare provider. "Better-engaged patients make better decisions," he says. "That's the benefit of transparency."

Yet some also say *ProPublica* has an anti-industry bias. Last March, *ProPublica* teamed with *The Boston Globe* on an exposé of Yoav Golan, an infectious disease specialist at Tufts Medical Center, in Boston, and a leading figure in the development of new antibiotics, who had accepted speaking, consulting and research payments from three drug companies, totaling $137,840 in 2012. Golan's activities had all been scrutinized for potential conflicts of interest and approved by his own department at Tufts. Yet the headline read "Double-dip: doctors paid to advise, promote drug companies that fund their research"[5]. That prompted a sharp rebuke by Ford Vox, a physician and contributing editor at *Forbes Magazine*, who claimed the coverage "typifies a growing gotcha genre of health journalism that portrays doctors as the enemy in a struggle for honesty and openness in medicine"[4].

Ornstein emphasizes that *ProPublica* takes "great pains to differentiate research payments from other payments," and that Dollars for Docs and the OPP both have the same goal, which is to make healthcare consumers more knowledgeable. However, he feels the issue of physicians having multiple relationships within industry is important and that the public should have all the information in evaluating research and patient care. "Without these disclosure efforts, you would have no way to know how to assess your doctor's potential ties with industry," he says.

of opacity—if the research is transparent, then the products have to be really good, and hopefully that will result in less death and injury to patients."

Taking the opposite view, Thomas Stossel, a senior physician in the hematology division at Brigham and Women's Hospital and Harvard Medical School, both in Boston, counters that the OPP will merely "provide a huge boondoggle for lawyers and those in the media who want to sue and embarrass companies." Describing the OPP as "300 pages of gibberish," Stossel insists the current system is self-policing with respect to conflicts of interest, and he warns that companies subjected to onerous financial reporting requirements will simply "move their clinical trials to Croatia!" (Sources with Pfizer, Millennium and Sucampo say the OPP would have no bearing on where they conduct clinical research.)

MGH's Clark takes a middle view. Industry's underlying motivation is to make a profit, he acknowledges, whereas MGH is motivated mainly to conduct hypothesis-driven research, "and there is a certain amount of tension between those two objectives." But Clark adds that industry supplies more than funding—companies offer the back-and-forth collaborations and resources that hospitals and universities need to convert early-stage inventions into useful products, he says. The challenge now will be to ensure that transparency doesn't thwart conflicts of interest by suppressing the relationships that drive innovation. "The OPP is going to generate a lot of data about financial transactions, and we hope to use these data to educate the public about what we value in our relationships with industry," Clark says. "If a doctor gets a certain amount of money from a company, it shouldn't be seen as a stain." Clark says that he's now conducting internal presentations, and helping doctors register with the OPP so they can get access to the reporting data. "We need to be sure they can take advantage of the dispute period in the event that something has been reported incorrectly," he says.

Knapp—who notes Sucampo couldn't function without its ability to work with doctors, PhDs and hospitals—says that despite the regulatory burden, he welcomes the opportunity to explain how the company works with its academic partners. But Brachman warns that this opportunity will be lost if the OPP amounts to a data dump that lists transactions without any context. "If we don't reach our goal of bringing greater clarity across the system, then I would say this has been a colossal failure that accomplished nothing," she says.

CMS's Griner answers that the intent of the rule isn't to alter industry's relationships with doctors or hospitals one way or another. According to Griner, these relationships exist for positive reasons, but they're also prone to conflicts of interest. "So it's up to the doctors to make clear what they accept, and it's up to us to answer questions that patients and their families have about these relationships," she says. "All we're trying to do is get the information out there and to encourage more informed decisions about healthcare delivery."

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