Open Payments Program (aka the Sunshine Act) Makes Public Debut

By Charlie Schmidt

With government funding for biomedical research stagnant or declining, scientists rely more than ever on industry support. Yet although that support is indispensable, it poses delicate challenges: Scientists and doctors are sometimes tempted to decide what's best for a sponsoring company rather than for patients. These conflicts of interest have sparked growing calls for transparency into industry’s financial ties to the biomedical community.

A federal website, managed by the Centers for Medicare and Medicaid Services (CMS), will soon reveal virtually all transactions between the drug industry and its collaborators. Set to launch Sept. 30, the website represents the public face of the Open Payments Program (OPP)—a provision of the Affordable Care Act created to avert conflicts of interest in biomedical research and physician prescribing practices. OPP is better known by its former name, the Sunshine Act, and it requires drug and medical device companies to report all payments of at least $10 to doctors and teaching hospitals, ranging from meals and gifts to long-term support for clinical trials.

Worries Over Context

Even as stakeholders applaud OPP’s intentions, many worry that it could fuel misperceptions about industry’s role in bringing new treatments to market.

“The data have to be accurate and must provide the right context; otherwise, they’re meaningless,” said Richard Schilsky, M.D., F.A.C.P., F.A.S.C.O., chief medical officer of the American Society of Clinical Oncology. “The public must be able to distinguish legitimate research support from a company flying me to the Caribbean for a nice dinner and a marketing spiel.”

In addition to providing dates, recipients, and amounts of transactions, companies also could explain what the money was used for in a 500-character “context” field. However, CMS will not release a mockup of the public website, so how that context will appear to the public in September is unclear. This approach is disconcerting to researchers who worry that the data could appear as lump sums paid to individuals. Robert E. Harbaugh, M.D., chair of the neurosurgery department at Penn State University in Hershey, said that a proclivity for “gotcha” journalism makes the press look for names. Such journalism, he said, is more motivated to reveal industry abuses than to explain benefits of industry collaborations.

According to CMS spokesperson Courtney Jenkins, CMS plans to describe the nature of payments and other transfers of value available on the website as speaking fees, consulting fees, gifts, or research grants. Moreover, CMS has “extensive ongoing outreach campaign under way to educate and inform physicians,” she wrote in an e-mail. “That effort includes webinars, Open-Door Forums, articles in medical society publications, and via social-media outlets.”

Ramping Up for Transparency

Hospitals vary in their preparation for OPP. At Massachusetts General Hospital—which receives more industry money than any other U.S. hospital—administrators have urged physicians to participate in OPP’s review-and-dispute process. Christopher Clark, director of Mass General’s Office for Interactions with Industry, warns that physicians who are also investigators on industry-sponsored trials risk being mischaracterized as sole recipients of funding.

“People will think the dollars flow to individuals, and that’s not true,” he said. “This is a problem because many in the public attach negative baggage to industry
relationships, so we have to be careful that the data are reported accurately.”

Other hospitals have taken a more lackadaisical approach. Their administrators believe that their internal conflict-of-interest policies already account for OPP's requirements.

Yet Barrett J. Rollins, M.D. Ph.D., chief science officer with Boston's Dana–Farber Cancer Institute, counters that administrators should pay attention to what might appear in the OPP database. CMS reported in August that it temporarily took the review-and-dispute system offline because of inaccuracies in how at least one company reported some physician payments. Here, identities of different physicians with the same name but licensed in different states were erroneously combined. According to a CMS statement, “We believe this problem is limited to a small number of physicians, and we are working to fully assess and correct the issue. In the interim, we do not want physicians to see data which do not belong to them, so we are temporarily suspending Open Payments registration. We will also work with the responsible companies to make them aware of the issue and correct the root data.”

Rollins emphasized that the only way Dana–Farber and other cancer centers can improve treatments is to partner with companies with capacity for large-scale drug development. Still, he acknowledged that conflicts of interest pose a well-documented threat to medical decision making. Sometimes this happens even on a subconscious level, such as when physician–researchers are evaluating a patient's eligibility for a clinical trial or reporting whether an experimental drug caused an adverse event. Financial transparency can help protect against these scenarios, he said. Rollins also worries that OPP's scope is too broad, such that even writers and editors hired to help prepare peer-reviewed manuscripts constitute “transfers of value” to each author. “Does that rise to the level of something that the public needs to be aware of?” he asked.

Recalling the Medicare Part B physician payments publicly disclosed earlier this year, Schilsky said that many were deemed inaccurate after appearing in the media.

“Inaccurate data create a lot of needless anxiety,” he said. “If CMS can release complete, contextualized data, then it will have performed a valuable public service. If CMS can’t get the data to that point, then the numbers should not be released until they’re cleaned up and posted in a way that makes it possible for people to understand what they mean.”

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