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Forecast for the Physician Payment Sunshine Act: Partly to Mostly Cloudy?

Stephanie R. Morain, MPH, PhD,
Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD

Charles Flexner, MD,
Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, School of Medicine, Johns Hopkins University, Baltimore, MD

Nancy E. Kass, ScD, and
Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Jeremy Sugarman, MD, MPH, MA
Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, School of Medicine, Johns Hopkins University, Baltimore, MD

The Physician Payment Sunshine Act (PPSA) intends to bring greater transparency to physician-industry relationships. Following Justice Brandeis's observation that “sunlight is said to be the best of disinfectants,” the PPSA aims to shed light into financial relationships that may compromise patient care and research integrity.

Public reporting of financial relationships is already required in four states plus the District of Columbia, and at least 13 pharmaceutical companies now disclose information through quasi-voluntary agreements reached through settlements with the Department of Justice (1). Nevertheless, the PPSA dramatically expands transparency, extending both the scope of disclosure and the degree of public accessibility. Under the new program, now known as “Open Payments,” manufacturers of drugs, devices, biologics, and medical supplies must report nearly all transfers of value made to physicians or teaching hospitals (2). This information will be posted to a public website, scheduled to launch September 30, 2014 (3).

Among the PPSA's most notable expansions for disclosure are payments for research, including clinical trials (4). Unlike earlier disclosure requirements, which generally focused on marketing, speakers' fees, and gifts, the PPSA creates a separate disclosure stream for research. Research payments will be distinguished from “general payments,” including speaking or consulting fees, gifts, royalties, and investment interests.

Corresponding author: Dr. Morain, Berman Institute of Bioethics, Johns Hopkins University, 1809 Ashland Ave, Baltimore, MD 21205; tel. (410) 614-5374; smorain1@jhu.edu.

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Establishing two-tracks to distinguish research payments from other activities reflects recognition of the “special status” of research, including its social value in advancing health. Nevertheless, one part of the PPSA's requirements for disclosing research payments risks conveying a distorted image of certain physician-industry relationships.

Specifically, the Centers for Medicare and Medicaid Services (CMS), which issued the final regulations for the PPSA's implementation, not only requires reporting of industry funding of research projects, but, importantly, also requires manufacturers to report the value of pharmaceuticals provided for research, including those donated for federally funded clinical trials. Consequently, physicians conducting research involving donated drugs—a common practice within large networks funded by the National Institutes of Health (NIH) such as the Cooperative Oncology Groups and the AIDS Clinical Trials Group (ACTG)—will have the monetary value of those drugs listed as “research payments” within public databases. Reports will include the recipient physician's name, total payment amount, study name, and study drug (5). For research involving multiple investigators, the donation will be reported as a payment to the principal investigator, or, for multi-center trials, to each site's investigator of record.

For some studies, the reported value of these donations will be staggering. The NIH recently initiated a trial of sofosbuvir, a once-daily agent for hepatitis C, whose retail value is about $1000 per dose, with a course of curative treatment being 12 weeks or 84 doses (6). An investigator enrolling just ten patients would be reported as receiving $840,000 from Gilead Sciences, sofosbuvir's manufacturer. Similar reports will likely ensue for research involving donated oncology drugs, whose annual costs for a single patient can easily exceed $100,000 (7).

Attributing such large payments to individual physician-investigators seems inconsistent with the PPSA's intent. Donated drugs are intended for use by patients, and do not provide direct monetary value to physician-investigators. The PPSA rules cloud this critical distinction. The NIH encourages the use of donated drugs, and an investigator committed to conducting federally funded research may have little choice but to inappropriately *appear* to have received industry payments. Of note, while CMS requires manufacturers to report drugs donated for clinical trials, they are not required to report transfers intended for patient use in non-research settings, including product samples, educational materials, and in-kind items to be used for charity care (8).

It is unclear how patients or the general public will interpret disclosures of donated drugs, particularly when their value seems poised to dwarf that of reimbursements for speaking or consulting activities. One may presume that the public may have difficulty distinguishing between donated drugs for research and transfers of financial value to physicians. Such confusion frustrates the purpose of the PPSA, casting shadows where bright light had been promised.

Confusion over reporting for donated study drugs may also have a chilling effect on physicians' willingness to participate in research, should physicians choose to avoid the appearance of financial relationships that raise the potential for misinterpretation.

What should be done given such possible confusion? One response would be to exclude drugs used in research from reportable research payments, as is done for clinical care. Although CMS received numerous recommendations regarding exclusions during PPSA's public comment period, it declared that it lacks the statutory authority to add exclusions beyond those explicitly outlined in the legislation (9). Congress would instead have to pass new amending legislation—a dubious prospect, given the low priority of such a request. Alternatively, for federally sponsored research, drugs could be reported as donations to the federal government rather than to individual researchers. Since federal agencies often encourage these drug donations, such an approach better represents the true relationships at stake. However, this approach would not resolve analogous issues with non-federal sponsors.

Absent such changes, several modifications could reduce the potential for misinterpretation. First, donations could be attributed to research sites (such as medical centers), rather than to individual physician-investigators. Second, CMS could add a category for reporting research payments, to distinguish donations for which the physician receives no direct financial benefit. Third, manufacturers could be *required* to include a brief descriptive statement when disclosing drug donations providing additional context. Under current rules, manufacturers may provide contextual information to support meaningful interpretation, such as stating that the drug was provided for the conduct of a research study, but they are not required to do so. Requiring such disclosures could improve data interpretability.

The public deserves accurate, accessible information regarding third party payments to physicians that may affect their care. Yet disclosures must be presented in a manner not prone to misinterpretation. Misinterpretation, or fear of it, could undermine physician participation in important health research. As such, the effects of implementation should be monitored and CMS should consider appropriate revisions to truly let the sun shine on important issues.

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