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

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The Physician Payment Sunshine Act (PPSA) intends to bring greater transparency to physician–industry relationships. A reference to Justice Brandeis' observation that "sunlight is said to be the best of disinfectants," the PPSA aims to shed light on financial relationships that may compromise patient care and research integrity.

Public reporting of financial relationships is already required in 4 states plus the District of Columbia, and at least 13 pharmaceutical companies now disclose information through quasi-voluntary agreements reached through settlements with the U.S. Department of Justice (1). Nevertheless, the PPSA dramatically expanded transparency, extending 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 Web site, scheduled to launch 30 September 2014 (3).

Among the PPSA's most notable disclosure expansions are for 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. These payments will be distinguished from "general payments," including speaking or consulting fees, gifts, royalties, and investment interests.

Establishing 2 tracks to differentiate research payments from other activities reflects recognition of the "special status" of research, including its social value in advancing health. Nevertheless, 1 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 & Medicaid Services (CMS), which issued the final regulations for the PPSA's implementation, requires not only that investigators report industry funding of research projects but also, importantly, that manufacturers report the value of pharmaceuticals provided for research, including those donated for federally funded clinical trials. Consequently, for physicians doing research involving donated drugs—a common practice in large networks funded by the National Institutes of Health (NIH), such as the cooperative oncology groups and the AIDS Clinical Trials Group—the monetary value of those drugs will be listed as "research payments" in 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 multicenter 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 virus infection whose retail value is approximately $1000 per dose, with a 12-week course of curative treatment, or 84 doses (6). An investigator enrolling just 10 patients would be reported as receiving $840 000 from Gilead Sciences, sofosbuvir's manufacturer. Similar reports will probably ensue for research involving donated oncology drugs, for which the single-patient annual cost 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 doing federally funded research may have little choice but to inappropriately *seem* to have received industry payments. Of note, although CMS requires manufacturers to report drugs donated for clinical trials, they are not required to report transfers intended for patient use in nonresearch settings, including product samples, educational materials, and in-kind items to be used for charity care (5).

How patients or the general public will interpret disclosures of donated drugs is unclear, 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 they 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 many recommendations about exclusions during the PPSA's public comment period, it declared that it lacks the statutory authority to add exclusions beyond those explicitly outlined in the legisla-

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tion (5). Congress would instead have to pass new amending legislation—a dubious prospect, given the low priority of such a request. As an alternative, drugs for federally sponsored research could be reported as donations to the federal government rather than to individual researchers. Because federal agencies often encourage these drug donations, such an approach better represents the true relationships at stake. However, it would not resolve analogous issues with nonfederal sponsors of research.

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 that provides additional context. Under current rules, manufacturers may provide contextual information to support meaningful interpretation, such as stating that the drug was provided for a research study, but they are not required to do so. Requiring such disclosures could improve data interpretability.

The public deserves accurate, accessible information about 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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