The Physician Payments Sunshine Act.
New regulations require medical product manufacturers to publicly report payments made to physicians and teaching hospitals.

WHAT’S THE ISSUE?
The Physician Payments Sunshine Act (PPSA)—also known as section 6002 of the Affordable Care Act (ACA) of 2010—requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals. It also requires certain manufacturers and group purchasing organizations (GPOs) to disclose any physician ownership or investment interests held in those companies.

The data will be published annually in a publicly searchable database. The first data collection period began in August 2013, and the deadline for submission to CMS was in March 2014. These data will be aggregated and made available to physicians and manufacturers for review and correction, and will then be published on a public website. The first wave of data went live September 30, 2014. The initial intent was to publish all data by this date, but CMS announced in August that some data will be withheld pending further verification.

The full impact of this law will not be clear until several years after its implementation, and ongoing questions remain regarding its effects on patient decision making, physician–industry relationships, and the conduct of clinical research and dissemination of its results.

WHAT’S THE BACKGROUND?
Financial relationships between physicians and medical product manufacturers are common and can include everything from free meals to consulting or speaker fees to direct research funding. These relationships can have many positive outcomes and—particularly in the context of consulting and research funding—are often a key component in the development of new drugs and devices. However, they can also create conflicts of interest and in some cases can blur the line between promotional activities and the conduct of medical research, training, and practice.

A 2009 nationwide survey found that nearly 84 percent of physicians had some form of financial interaction with manufacturers of drugs, devices, biologicals, and medical supplies, the majority of which were meals provided in the workplace. Nearly 20 percent received reimbursements for attending meetings or continuing medical education (CME) events, and slightly fewer than 15 percent received payments for professional services. These numbers were significantly lower than...
those found in a similar survey conducted five years earlier. This decrease was likely linked to a number of factors, including broader changes within the pharmaceutical industry (which were accelerated by the financial crisis) that led to reductions in salesforce staff and shifting marketing strategies.

Another factor in this decrease may be the growing awareness among researchers and policy makers of the ways that physician-industry relationships can bias physician decision making, encourage inappropriate prescribing that drives up health care costs, and undermine the independence and rigor of clinical research. Over the past decade various professional bodies, academic institutions, and medical journals have implemented conflict-of-interest policies aimed at mitigating industry influence on medical education and research. There have also been a number of attempts to increase transparency around these relationships, in the hopes that disclosure would help to reduce their negative consequences without unnecessarily blocking constructive partnerships.

Laws have been passed in at least five states and the District of Columbia, requiring that manufacturers of drugs, devices, biologicals, and medical supplies report various details of their financial relationships with clinicians. At the federal level, the National Institutes of Health requires all grantees to disclose significant financial relationships with manufacturers, while the Food and Drug Administration (FDA) requires drug sponsors to report on any financial ties with clinical investigators that reach certain monetary thresholds (which are higher than those set by the Sunshine Act). In addition, certain pharmaceutical and medical device companies have been required to disclose these relationships as part of legal settlements with the Department of Justice.

However, these data are scattered across multiple sources, may require formal disclosure requests, and are of variable quality and completeness. Several of the laws also exclude medical device manufacturers. In 2008 and 2009, respectively, the Medicare Payment Advisory Commission and the Institute of Medicine published influential reports on physician conflicts of interest. Both documents highlighted the need for greater transparency around physician-industry relationships as part of a broader strategy for addressing conflicts of interest. Both documents also called for the establishment of a standardized, nationwide, mandatory public reporting program, which could supplement or replace the patchwork reporting system currently in place.

At around the same time, efforts were underway in Congress to establish just such a system. Senators Chuck Grassley and Herb Kohl first introduced the Physician Payments Sunshine Act in 2007, which failed to pass. However, its provisions were subsequently amended and incorporated into the ACA as section 6002. Following an extensive public consultation process, the final rule for implementing the PPSA was published in the Federal Register in February 2013. The reporting period began in August 2013.

### What’s in the Law?

The PPSA requires manufacturers of drugs, devices, biologics, and medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program to report to CMS on three broad categories of payments or “transfers of value” (see Exhibit 1 for additional information on the reporting process). The first of these categories covers general payments or transfers of value such as meals, travel reimbursement, and consulting fees.

The second reporting category applies to ownership and investment interests in manufacturers held by physicians as well as their immediate family members. In addition to manufacturers, certain group-purchasing organizations (GPOs)—entities that negotiate pharmaceutical contracts on behalf of health care providers—and all physician-owned distributors of medical devices are also expected to report.

The third broad category of reporting covers research payments. This includes any payment made for participation in preclinical research, clinical trials, or other product development activities. To qualify as research under the final rule, it must be subject to a written agreement or a research protocol. However, the amount of these payments will be presented through a separate reporting stream. This is done to reflect the fact that a research grant made to an investigator typically flows through a host organization and may not directly accrue to the physician leading the research.

While these categories cover a very wide range of relationships, certain transactions and transfers are exempt from disclosure. Manufacturers are not required to report on...
any payments under $10 (unless those individual payments total more than $100 annually), on educational materials intended solely for patients, or on product samples (see Exhibit 1). However, under a separate provision of the ACA, manufacturers are required to submit data to the FDA on the identity and amount of samples requested and distributed to physicians. Revised draft guidance to manufacturers on these submissions was published in July 2014.

Other exceptions to annual reporting include payments made in support of products that are still under development, including generic products under development through an Abbreviated New Drug Application. In such cases, public disclosure will be delayed for four years or until FDA approval, whichever comes first. Off-label research on approved products, however, will not be granted any delays. Payments made to a CME organization to subsidize educational events will also be exempt from reporting, provided the event is accredited by a provider association (any one of five associations identified by CMS) and the manufacturer in question has had no direct role in the choice or compensation of the speaker(s). However, CMS recently announced that it may remove this CME exemption from the final rule for subsequent years’ reporting, arguing that these types of payments are already excluded under a separate exemption. Under this exemption, indirect payments or transfers of value—such as those made to third-party organizations—are excluded if the manufacturer is unaware of the identity of the recipient during the reporting year.

Reporting obligations began August 1, 2013, and the deadline for reporting all 2013 payments was March 31, 2014. Reporting is done through the National Physician Pay-
The Physician Payments Sunshine Act (also known as the Open Payments program), established within CMS to manage this process. Once the data are collated and posted, manufacturers, GPOs, physicians, and teaching hospitals have forty-five days to review the data attributed to them and fifteen days after that to dispute and correct the data. If the dispute has not been resolved within fifteen days, CMS will still publish the data but will note that they are under dispute. Any subsequent changes to the reported data will be made when the data are refreshed in the next calendar year. Data for the period of August 1, 2013 to December 31, 2013, were published September 30, 2014.

The PPSA also imposes penalties for failure to comply with these reporting requirements. For each payment that a manufacturer or GPO fails to report, a penalty of $1,000–$10,000 may be applied. The maximum annual penalty for failure to report is $150,000. The penalties are more severe in cases where the manufacturer or GPO knowingly fails to report. These penalties range from $10,000–$100,000 per payment, up to a maximum penalty of $1 million.

The final rule also stipulates that compliance with the provisions of the PPSA does not exclude any manufacturer, GPO, physician, or teaching hospital from civil liability related to those payments. Any payment or transfer of value that is currently prohibited under the Anti-Kickback Statute, the False Claims Act, or other health care fraud and abuse laws may still be subject to fines, sanctions, or lawsuit. Indeed, one of the potential impacts of the law will be to draw regulators’ attention to financial ties that may warrant further investigation.

What’s the Debate?

Most of the debate surrounding implementation of the PPSA centers around two general issues: the administrative and legal challenges of establishing a nationwide public reporting system; and how reporting will ultimately affect the behavior of patients, providers, and industry.

Administrative and Legal Issues

Both manufacturer and provider representatives have raised concerns about the reporting burden associated with the Open Payments program, as well as the challenges associated with correcting inaccurate reports. CMS has taken steps to minimize the burden where possible and estimates that the overall cost of reporting will total $269 million in the first year and $180 million each following year. These costs will accrue mostly to manufacturers and GPOs, though physicians may incur some costs in verifying and correcting the reports.

However, there are ongoing concerns among providers regarding the process for disputing reported payments. A number of medical associations and societies recently drafted a letter to CMS outlining these concerns, arguing that the physician registration process was too complex and that the timeline for dispute was too condensed to allow physicians to properly address inaccurate information. These groups also challenged CMS’s proposal to remove the CME exemption, arguing that it would be too difficult to ensure that a manufacturer does not learn the names of particular event speakers once that event has taken place.

The PPSA also presents challenges in terms of its alignment with existing state laws. While the act generally preempts existing state laws where they require reporting the same information by the same entities, the scope of exceptions to this preemption is unclear, and the act does not preempt all state-level reporting requirements. Some states, for example, require reporting for payments made to nurse practitioners and physician assistants, not just physicians. Others may require the data in different formats, thus requiring the manufacturer to report the same data multiple times.

Consequences of Public Reporting

Most of the debate centers on the consequences of public reporting. It is not yet clear how these data will be used once published; how they will be interpreted; or what impact they will have on individual behaviors, the practice of research, or policy makers’ approaches to regulating physician-industry relationships.

Both physician and manufacturer representatives have raised concerns over how patients will interpret this information. Three major trade organizations recently published a letter to CMS, voicing concern that they have not had the opportunity to review or consult with the agency on how key contextual information about those payments—specifically, what they were for or the circumstances in which they were received—will be presented to the public. They argue that without clear communication about the purpose and context of these transfers, it may be difficult to distinguish
payments that inappropriately influence prescribing from payments made for services that are helpful for innovation or clinical practice.

_Some physicians have further argued_ that the threshold for determining “appropriate” physician-industry interaction is not always easy to establish and may vary according to specialty fields or practice settings. Even given this contextual information, it is not clear how it will affect patients’ decision making.

Concerns over public misperception may, in turn, have unpredictable effects on physicians’ behavior. Physicians may take any number of steps to preempt the appearance of a conflict, perhaps unnecessarily limiting their interactions with manufacturers to the detriment of their education about new technologies or their participation in clinical research.

The effects of reporting on manufacturer practice are also unclear. The PPSA excludes certain categories of providers who may have prescribing power, such as physician assistants, nurse practitioners, and medical residents. Manufacturers may thus be incentivized to shift financial relationships to those categories. Others note that manufacturers were already moving away from traditional physician-marketing approaches before reporting even went into effect.

In the past few years, for example, some pharmaceutical companies have significantly reduced payments to physicians for speaker fees or have announced that they will no longer pay speaker fees at all. It is not clear how much these changes relate to the PPSA, rather than to broader changes in the drug and device market and the impact of increased regulatory scrutiny. These changes include the rise of direct-to-consumer advertising, as well as increased marketing to payers (which often act as the gatekeepers for prescription drug use). Companies are also increasingly relying on clinical research professionals (known as “medical scientific liaisons”), who often have an advanced medical, pharmacy, or science degree, to market their products to a broad range of audiences, including health care professionals, patient associations, academic institutions, and other stakeholders. Taken together, these broader changes may partly undermine the goals of the PPSA by encouraging the substitution of one form of undue influence for another.

**WHAT’S NEXT?**

The first year of implementation has presented a number of technical challenges for CMS. The agency’s website has twice experienced glitches that required it to shut down, and physician reports of inaccurate data have prompted the agency to withhold as much as one-third of the data that were reported for the first year. Industry trade groups have raised questions regarding the reasons for withholding this much information, arguing that these companies reported their data in a manner consistent with the CMS guidelines.

Nevertheless, the bulk of the data was published in September 2014. It is unclear when the rest will be released. The agency may also revisit certain aspects of the final rule for reporting requirements. However, these administrative challenges will eventually be resolved.

The full effects of the PPSA will likely not be felt for several more years, as industry and physicians adapt to its requirements and the broader public responds to the information that becomes available. Indeed, it may be difficult to empirically measure the ultimate effects, as these data were not widely or systematically reported before the PPSA was enacted.

However, even those who champion the program agree that simple disclosure is not sufficient to address financial conflicts of interest. Physicians and research centers will also need a reliable framework for determining what kinds of relationships are appropriate, useful, and beneficial. More work is required to ensure that financial conflicts of interest are monitored and regulated appropriately.

Department of Health and Human Services, “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule,” Federal Register 78 no. 27 (2013): 9458–528.

Institute of Medicine, Conflict of Interest in Medical Research, Education, and Practice (Washington, DC: IOM, April 2009).

