What is the Physician Payments Sunshine Act or “Open Payments”? 

I. Introduction

Over the last several decades, Americans have enjoyed tremendous improvements in overall health outcomes and a better quality of life, with declining death rates for heart disease, stroke, cancer, and HIV/AIDS. Many of these advances have been achieved through collaboration between physicians, teaching hospitals, and pharmaceutical and medical device manufacturers. In fact, approximately 83 percent of physicians have some type of relationship with industry, such as conducting clinical trials and training physicians on how to safely use a new device. A physician survey conducted in 2003

and 2004 found that pharmaceutical companies paid more than a quarter of physicians in the preceding year for consulting, giving lectures, or enrolling patients in clinical trials.\(^3\) In 2005, manufacturers spent nearly $7 billion on physician detailing and provided free samples with a retail value of more than $18 billion.\(^4\) Researchers and faculty at academic medical centers (AMCs), as well as accredited continuing medical education (CME) providers, also receive funding from industry.

Physicians rely on interactions with manufacturers because many do not have the time or resources to stay educated and informed about constantly changing and evolving treatments, clinical data, and other important information. For example, primary physicians spend 55 percent of their day on face-to-face interactions with patients; 14.5 percent of their day on visit-specific work outside the exam room (e.g., medical record review, notes, prescriptions, or tests); 23 percent of their day on work related to patients not currently being seen (e.g., questions, calls, insurance); and 7.5 percent of their day on administrative and academic activities and other patient care (e.g., home visits, research).\(^5\) These physicians are overworked and at full capacity with patients, and they face increasing administrative and regulatory burdens with electronic health records (EHRs), quality measures, and other healthcare reform–related obligations—all of which means physicians have less time to read the approximately 341 relevant medical journals and 7,287 monthly articles (roughly 627 reading hours per month) needed to stay up to date on all medical literature.\(^6\)

Physicians turn to multiple sources of information to make decisions about treatments and care, including (1) their clinical

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6. Id.
knowledge and experience; (2) their patients’ responses to particular medicines; (3) each patient’s particular situation, which might include drug interactions, side effects, and contraindications; (4) clinical practice guidelines; (5) discussions with colleagues/peers; and (6) articles in peer-reviewed journals. A 2012 Deloitte survey showed that a physician’s best means for learning about new medications and treatments are through industry-supported CME programs (52 percent), medical journals (51 percent), industry interactions (17 percent), colleagues (14 percent), and Internet (including social media) content (13 percent). Physicians weigh all of this information when making the best prescribing decisions for patients, and 66 percent of physicians said they trust the information they get from industry.

A 2011 survey showed that more than 4 in 10 physicians find it difficult to stay informed about new medicines, but 79 percent said meetings and discussions with industry professionals help ensure that they stay current on medical information while balancing heavy workloads to address these concerns. As physicians’ time becomes more and more limited, sometimes the only available time to meet with an industry professional to catch up on the latest developments related to medicines is over a brief lunch break or an after-work dinner, which is typically modest in nature. Accordingly, manufacturers and their agents or representatives use interactions and activities to keep physicians abreast of emerging safety, benefit, and risk information; new studies and the latest clinical information and trial results; appropriate dosing; new FDA-approved drugs and treatments; and new indications, as appropriate. Such information is critical to physicians because it could affect their decisions about appropriate patient care. For example, many medicines require post-approval research to ensure that they are being used safely and appropriately. By meeting with physicians to convey such information, such as

particular safety concerns, companies ensure that patients using that product are provided with alternatives to avoid a treatment gap.

Manufacturers and agents or representatives also engage with physicians to discuss the ways their patients respond to the company’s medicines beyond a controlled clinical trial setting and to discuss disease challenges more broadly. These in-person meetings provide a level of detail that a physician cannot get through literature alone. In addition, physicians can ask questions specific to a medicine that the industry professional has deep expertise and knowledge about, or the professional can refer the physician to the company’s medical liaison for more specialized information. These conversations enable physicians to share real-world feedback on how well the drugs and devices are working, how patients react to prescribed medicines or treatments, patient compliance, and any side effects. This information helps companies make improvements and advancements for patient care and can prompt manufacturers to conduct additional research that could translate into a product change or beneficial new treatment protocols.

Physician meetings with manufacturers are also critical because physicians learn about company-sponsored programs that offer free or discounted treatments from their doctors to patients who do not have prescription drug coverage. This helps ensure that patients can actually take their medicines as prescribed, which can benefit their health and reduce the need for hospitalizations and other expensive medical care. Such meetings also ensure, in compliance with federal and state law, that physicians can give samples to patients to help start treatment early or to determine proper dosing or any unwanted side effects. In addition, physicians participate in manufacturer-sponsored educational and informational programs, which the majority of physicians find critical to gaining knowledge or skills helpful to their practice.8

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Physicians who attend and present or speak at these events do so to (1) expand and improve their clinical knowledge, (2) learn about potential side effects of medicines, (3) learn about new uses for medicines, (4) learn about the latest clinical data, and (5) learn about the range of treatment options and emerging safety and risk information. Many of these programs could not take place without the sponsorship of manufacturers, and such programs fill educational gaps particularly for primary-care and rural physicians who have limited peer interactions and access to professional conferences.9 Face-to-face meetings and educational programs sponsored by manufacturers also permit physicians to interact with each other and learn about complex disease states and available treatments and to capture detailed information that is otherwise buried in literature. Moreover, in-person education allows for an open discussion about advancements made in patient health and medical innovation. This kind of interaction helps physicians and their peers gain a better understanding of specific therapies and also provides a forum for those who might have questions about treatment options.

While the majority of these relationships and interactions are beneficial to the continued innovation and improvement of America’s healthcare system, some have expressed concern that “payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs.”10 However, there has been “no empirical basis for estimating the frequency of such problems.”11 Some have claimed that these relationships may also influence physicians’ behavior in ways that

9. Id. (noting that a manufacturer-sponsored educational event led by a well-qualified physician may be their most convenient opportunity to learn the latest information on treatments and that 86 percent of rural physicians attend manufacturer-sponsored education programs).
10. Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting the Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9518 (Feb. 8, 2013) [hereinafter Final Sunshine Rule].
11. Id. at 9519.
undermine their independence and objectivity in prescribing, teaching, learning, and practice. For example, some studies have shown that physician interactions with industry are associated with a greater willingness to prescribe newer, more expensive drugs.\(^\text{12}\) There has also been concern that clinical research funded by manufacturers is not transparent and may be more likely to reach conclusions favorable to the sponsor than non-industry-sponsored studies.\(^\text{13}\) 

In response to heightened legal and public scrutiny of physician–industry relationships—including a number of high-profile cases and investigations involving improper payments from manufacturers to physicians—industry and physician groups, such as the American Medical Association (AMA), the Pharmaceutical Research and Manufacturers of America (PhRMA), the Advanced Medical Technology Association (AdvaMed), and the Medical Device Manufacturers Association, developed voluntary guidelines to manage interactions between manufacturers and physicians.\(^\text{14}\) In addition, a growing number of AMCs, professional medical associations, medical journals, and clinical guideline–writing committees have adopted stringent rules for interactions with industry. Further, several states\(^\text{15}\) have enacted transparency laws that require manufacturers to report to state agencies payments made to physicians, hospitals, and other healthcare professionals (HCPs). Those payments are posted on a public website for patients and consumers to use when evaluating their physician’s recommendation for a particular treatment.


15. These include Minnesota, Vermont, West Virginia, Massachusetts, and Washington, DC.
In some cases, these state laws have also banned manufacturers from making certain payments or transfers of value to physicians, institutions, or HCPs licensed in their state (known as a “gift ban”). Notwithstanding these developments, some have expressed concern that industry guidelines are voluntary, and states have been criticized for posting payment data on websites that are unsearchable or difficult to access.

Proponents of transparency laws argue that comprehensive information about physicians’ financial relationships with manufacturers would help payers and health plans examine whether and to what extent industry ties influence physicians’ practice patterns, such as the drugs they prescribe and the procedures they perform. Such laws, proponents argue, would also enable patients to make better-informed decisions about physicians and treatments. Transparency laws might also deter physicians from participating in improper arrangements that violate industry and professional standards, which can sometimes lead to increased healthcare costs. Public reporting may also allow AMCs to verify the financial interests of their clinical investigators and help media and researchers shed light on physician–industry interactions and identify potential conflicts of interest.

Despite these arguments, government officials have acknowledged that support “for greater transparency does not imply that all—or even most—of these financial ties are inappropriate or undermine physician–patient relationships.” In fact, much collaboration between researchers and industry has benefited patients by translating research discoveries into new drugs and devices. In addition, manufacturers’ marketing efforts may lead to increased use of beneficial drugs and devices and keep physicians informed about new safety data, such as black box warnings. Moreover, a public reporting system might discourage physicians and other providers from having

16. Final Sunshine Rule at 9510.
17. Title: Hearing on Doctors and the Drug Industry before the S. Special Committee on Aging, 110th Cong. (2007) (statement of Marjorie E. Powell, Pharmaceutical Research and Manufacturers of America).
legitimate research, consulting, education, and training arrangements with manufacturers that benefit patients and pose little risk of abuse.18

Given these concerns, coupled with the growing amount and scope of industry involvement in medical research, education, and clinical practice, the Medicare Payment Advisory Commission (MedPAC) and the Institute of Medicine (IOM) recommended in 2009 that Congress enact a new regulatory program to address transparency in physician–industry relationships.19 This led Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) to propose the Physician Payments Sunshine Act (“Sunshine Act”), which was eventually included in Section 6002 of the Patient Protection and Affordable Care Act (ACA). The Sunshine Act20 requires “applicable manufacturers” of drugs, biologics, devices, or medical supplies covered under Medicare, Medicaid, or the Children’s Health Insurance Plan (CHIP) to report annually to the Centers for Medicare and Medicaid Services (CMS), in an electronic format, certain payments or other transfers of value made to “covered recipients”—physicians and teaching hospitals.21 The Sunshine Act requires CMS to post these payments and other payment-related information on a public website, now referred to as Open Payments, that is searchable, understandable, easily aggregated, and downloadable. CMS published a portion of data reported by applicable manufacturers for 2013 on September 30, 2014.22 For each subsequent year, applicable manufacturers

18. For example, a survey of over 1,000 physicians found that 66 percent would reduce their interactions with industry if false or incorrect information was disclosed. See Thomas Sullivan, Physician Payment Sunshine Act: Recent Survey Shows Physicians Still Unaware and Hospitals Concerned about Impending Regulation, POL’Y & MED. (Sept. 19, 2012), http://www .policymed.com/2012/09/physician-payment-sunshine-act-recent-survey-shows-physicians-still-unaware-and-hospitals-concerned-about-impending-regulation.html.
20. Final Sunshine Rule at 9518.
21. The law also applies to applicable group purchasing organizations (GPOs).
22. The first reporting period only captured payments or transfers of value during the period of August 1, 2013, to December 31, 2013, and, as widely reported in the trade press,
must submit payment data to CMS by the 90th day of each calendar year, and CMS must post this data on Open Payments by June 30 of each year.

This guide provides a detailed overview of the Sunshine Act, transparency initiatives, and related implications associated with increased attention on physician–industry relationships. Section II provides background and the legislative history of the Sunshine Act. Section III provides a detailed summary and analysis of the technical statutory and regulatory requirements manufacturers and group purchasing organizations must abide by to comply with the law. Section IV analyzes the Sunshine Act’s regulatory requirements as they may impact other healthcare fraud and abuse and compliance obligations and requirements, including the Anti-Kickback Statute and the False Claims Act. Section IV.C provides an overview of related state transparency laws and gift ban laws, including how such provisions are preempted under the Sunshine Act. Finally, Section V offers a brief overview of CMS’s first data release on the Open Payments website and discusses potential issues and future concerns for all stakeholders moving forward.

II. Background and Legislative History of the Physician Payments Sunshine Act

Long before Senators Grassley and Kohl proposed the Sunshine Act, several states enacted transparency and gift ban laws in the early 1990s. With Minnesota leading the pack, several states, along with the District of Columbia, slowly began to enact laws requiring pharmaceutical and medical device manufacturers (in some cases) to either disclose certain payments or transfers of value that their companies made to HCPs licensed in those states, prohibit certain payments to HCPs, or adopt compliance programs in accordance

does not include complete data for this five-month period due to significant technical issues and problems.