



Sunlight as Disinfectant — New Rules on Disclosure of Industry Payments to Physicians

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small-value gifts.⁵ The discrepancy between data sets also raises the possibility that some qualifying payments were not reported to the Massachusetts database.

The federal Physician Payment Sunshine Act will soon require manufacturers to report most payments to physicians and teaching hospitals on a national level. Recently released rules indicate the intent to create a searchable system that will include the names of drugs or devices related to the payment. Descriptors for the type of relationship will be included as well, although the ones currently used in Massachusetts are of limited value, since the dominant category of “compensation for bona fide services” encompasses legitimate scientific as well as more contro-

versial marketing relationships. However, many types of indirect payments, such as those made through intermediary organizations that host CME conferences, will be exempt from the national reporting requirement — which raises the possibility of some undetected payments. Nonetheless, the transparency offered by state or federal disclosure databases could be used in the future to explore relationships between financial interactions and health care outcomes or costs.

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Sunlight as Disinfectant — New Rules on Disclosure of Industry Payments to Physicians

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After extensive public comment, the Centers for Medicare and Medicaid Services (CMS) issued final regulations in February implementing the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act.¹ The 287-page document details requirements for producers of drugs, biologics, devices, and medical supplies to disclose virtually all transfers of value to physicians and teaching hospitals. The provisions were intended to help patients make more informed decisions and to deter financial relationships that might inflate health care costs.¹ The rules go well beyond preexisting law but stop short of directly regulating

financial relationships. Given that CMS projects compliance costs to industry of nearly \$1 billion over 5 years, it is reasonable to ask what benefits disclosure is likely to bring.

Payment-reporting laws have been enacted in six states and vary in the scope of covered payers and providers, types and minimum value of reportable payments, and restrictions placed on permissible payments. Some laws have substantial shortcomings, and data from the states have not been widely shared with the public. The federal law rectifies these problems, requiring public disclosure and comprehensive, standardized payment reporting.

The new rules thus inject a welcome dose of sunshine — but will they have the intended effects? Both theory and evidence suggest that the benefits of disclosure are unlikely to be realized solely through environmental exposure of patients to this information. Activating “learned intermediaries,” such as health insurers, however, could be a game changer.

Under the new rules, manufacturers must annually report transfers of value to licensed physicians or teaching hospitals exceeding \$10 per instance or \$100 per year, along with the recipient's identity and the purpose of the payment (see the Perspective article by

Agrawal et al. in this issue of the *Journal*). Some exclusions apply, including most honoraria to speakers in accredited continuing medical education programs and product samples and gifts primarily benefiting patients. Penalties for not reporting are at least \$1,000 per instance and up to \$150,000 per reporting period (for knowing violations, penalties increase by a factor of 10).

Beginning in September 2014, CMS will post reports on a publicly accessible website in a searchable format within 90 days of receipt. Only physicians' National Provider Identifier numbers will be omitted. To protect companies' proprietary interests, CMS will delay publishing information on payments for research activities relating to new products and non-clinical investigations of new uses of approved products for 4 years or until after approval is granted by the Food and Drug Administration.

CMS evidently intends to publish the data after aggregating payments in some unspecified way. The agency asserts that the statute requires aggregation,¹ although in fact it merely requires that the information be posted in a format that is "easily aggregated and downloaded."² This is an important distinction, since it is unclear whether the public data set will permit scrutiny of individual payments or whether analysts must apply for access to nonpublic information.

Transparency's appeal as a mechanism for achieving health policy goals transcends the policing of conflicts of interest. Improving the free flow of information on health care quality and cost has been a federal policy priority for at least two decades. Transparency is favored as a means

of improving health care delivery because it buttresses rather than constrains markets, avoiding the need for more intrusive, direct regulation. As the newest tributary in this stream of regulation, the Sunshine Act supplements many financial conflict-of-interest disclosure requirements for researchers, including those imposed by medical journals, institutional review boards, and the National Institutes of Health.

Disclosure rules aim to influence the behavior of both the subjects of reporting and those making decisions about whether to do business with them. Thus, one mechanism through which the Sunshine Act could reduce health care costs is that patients, having learned of a physician's involvement with industry, might alter their view of the physician's trustworthiness. They might be less inclined to accept treatment recommendations from these physicians or even to receive care from them. Given the evidence that greater physician financial involvement with manufacturers is associated with higher utilization of expensive, brand-name products, such dynamics could reduce costs.

Experience gives reason for skepticism about the potential force of patients' response to disclosures, however. Decades of public reporting of provider quality information have underscored the difficulty of engaging consumers in seeking even the most salient information about their providers, such as a cardiothoracic surgeon's predicted mortality rate, from a passive report.³ Consumers are typically unaware of these data and, even when they know about them, tend to choose their providers on the basis of other factors. The payment

data are also complex, and even with the educational information CMS plans to provide, patients may have difficulty evaluating the undesirable and beneficial aspects of various types of payments.

Alternatively, disclosure requirements could affect physician behavior. Physicians may avoid financial relationships with companies to guard against patient distrust, peer reproach, or becoming the target of a journalistic exposé or government investigation. To our knowledge, there is no published evidence about whether this type of disclosure deters physicians from accepting industry payments. Physicians might also maintain their relationships but be more careful about prescribing. A recent study showed that two state laws requiring reporting of physician payments had "negligible to small" effects on prescribing behavior, although those laws did not provide for public disclosure.⁴ Moreover, disclosure may affect physician behavior in perverse ways: experimental research has shown that disclosing financial incentives at the point of decision making led disclosers to make more biased recommendations, possibly to offset receivers' expected discounting of those recommendations or because disclosers believed that biased advice is acceptable if receivers have been warned.⁵

Overall, it seems unlikely that the mere existence of a payment-information repository will lead many patients or physicians to alter their behavior. Active use of the payment data by one or more expert intermediaries, however, could make a big difference, doing what patients cannot (or will not) do and raising the stakes for physicians.

The Securities and Exchange Commission (SEC) reporting requirements offer a useful analogue. Although SEC filings are publicly available, the target audience is institutional investors and financial analysts who have the expertise, time, and incentive to comb through this information and bring market discipline to SEC-reporting companies. Well-functioning financial markets thus offer a mechanism through which disclosure protects investors and deters corporate missteps.

Health insurers could serve as learned intermediaries for physician-payment data, taking physicians' involvement with industry into consideration in network-design decisions and perhaps designating as "preferred" those physicians who receive no money from industry. Insurers are well resourced to perform this analysis and have an economic incentive to discourage relationships that promote the use of expensive drugs. They hold financial power, and their active surveillance would eliminate physicians'

perceptions that payment reports are inconsequential because no one is looking.

Researchers and watchdog organizations can also serve as valuable intermediaries. Their analyses can flag especially problematic relationships and help policy-makers decide whether to impose direct restrictions. They will be hobbled, however, if CMS restricts access to detailed, payment-level data.

In addition, increased scrutiny might cause manufacturers to change their behavior. Pharmaceutical-industry guidelines have already eliminated some emoluments to physicians, and companies may move further in that direction. Whether such a move would be, on balance, beneficial or harmful to public health depends on the extent to which industry payments to physicians support valuable scientific and clinical activities rather than promote inappropriate practices. Almost surely these effects coexist, but their respective weights have not been measured.

It's hard to argue with the premise that problematic incentives are a nettlesome cause of cost growth in health care or to find fault with the principle of transparency. But to have a real disinfecting effect, this sunlight must be filtered through the lens of a capable, motivated intermediary.

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The Sunshine Act — Effects on Physicians

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The new Physician Payments Sunshine Act requires public reporting of payments to physicians and teaching hospitals from pharmaceutical and medical device companies, as well as reporting of certain ownership interests (see box). Sponsored by Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) and supported by consumer advocates, the law covers meals, honoraria, travel expenses, and grants from manufacturers, as well as ownership or investment interests in

group purchasing organizations (GPOs), by physicians or members of their immediate family. Information will be posted on a public website that will identify physicians who have received payments or hold ownership. Data collection begins in August 2013, with public reporting starting in 2014, under the National Physician Payment Transparency Program (NPPTP) of the Centers for Medicare and Medicaid Services (CMS).

Interest in public disclosure was stimulated by the extent of

financial relationships between physicians and industry. A 2007 study revealed that 94% of U.S. physicians had a relationship with industry — 83% received gifts, and 28% received payments for professional services such as consulting or research participation.¹ Of the physicians reporting industry relationships, 60% were involved in medical education, and 40% in creating clinical practice guidelines. By 2001, industry had become the major source of research and develop-