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 policymakers 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-

Reporting Requirements of the Physician Payments Sunshine Act.*

Entities that must report transfers of value

- Drug and device manufacturers who manufacture at least one product covered by Medicare, Medicaid, or CHIP
- Group purchasing organizations and physician-owned distributors

Recipients whose payments must be reported

- All licensed physicians (doctors of medicine, osteopathy, dentistry, podiatry, optometry, or chiropractic medicine), regardless of participation in Medicare, Medicaid, or CHIP
- Teaching hospitals

What must be reported

- Any payment or transfer of value, including cash, cash equivalent, in-kind items or services, and stock.
- Consulting fees, compensation for services other than consulting, honoraria, gifts, entertainment, food, travel (including the destination), education, research, charitable contributions, royalties or licenses, current or prospective ownership or investment interests, speaker compensation for CME events, and grants
- Ownership and investment interests held by physicians and members of their immediate family

What need not be reported

- Payments of less than $10 (unless in aggregate these payments exceed $100 in a calendar year)
- Product samples, educational materials that directly benefit patients or are intended to be used by or with patients, trial loans of covered devices, discounts or rebates, in-kind items for charitable purposes, warranty services, dividends from publicly traded mutual funds

Timeline for implementation

- August 1, 2013: Data collection begins
- March 31, 2014: Data from August–December 2013 submitted to CMS
- April–September 2014: CMS aggregates data and makes available to affected parties to review, and if necessary, correct
- September 30, 2014: CMS releases data publicly

* CHIP denotes Children's Health Insurance Program, CME continuing medical education, and CMS Centers for Medicare and Medicaid Services.

ment funding, accounting for 55 to 60% of some $100 billion annually.[2] Commercial funding for continuing medical education (CME) has also increased; industry now pays for more than a third of all CME offerings.[3]

Prior efforts to increase disclosure of industry–physician financial relationships include a 2009 Institute of Medicine (IOM) report.[2] The IOM developed recommendations to "identify, limit, and manage [potential conflicts of interest] without affecting constructive collaborations with industry" and called for broad public transparency. The Medicare Payment Advisory Commission (MedPAC) has also published reports examining industry–physician relationships and proposed a national reporting program.[4,5] Medical and industry organizations, including the Association of American Medical Colleges, the American Medical Association, the American College of Physicians, the American Academy of Orthopaedic Surgeons, the Advanced Medical Technology Association, and Pharmaceutical Research and Manufacturers of America, have produced voluntary codes of ethics to manage physician–industry relationships.

A considerable amount of data is already in the public domain. Several states — including Maine, Massachusetts, Minnesota, and Vermont — require public reporting of financial relationships. And at least 13 pharmaceutical companies must post information about physician ties under "corporate integrity agreements" resulting from settlements with the Office of Inspector General of the Department of Health and Human Services. Some additional companies have voluntarily disclosed physician payments on public websites.

The two groups affected by the new program are the entities that must report — manufacturers and GPOs — and the physicians and teaching hospitals receiving payments. Three types of transfers will be reported and tracked: general payments, ownership and investment interests, and payments for research.

First, any prescription drug or device manufacturer operating in the United States ("applicable manufacturers") must report payments. That includes entities under "common ownership" (e.g., parent companies or subsidiaries of drug or device makers) that provide assistance or support in drug or device manufacture. Foreign companies that have a U.S. base of operations or that conduct activities in the United States, either directly or through agents, are included. Manufacturers producing even one drug, device, biologic agent, or medical supply for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program must report "transfers of value" to physicians and teaching hospitals related to all their products. Products are included whether they are paid

for separately or as part of a bundle, as when a device is included in a diagnosis-related group (DRG) payment.

Second, the law covers teaching hospitals and physicians, including all doctors of medicine, osteopathy, dentistry, podiatry, optometry, and chiropractic medicine — not only those enrolled in or billing Medicare or Medicaid. A "teaching hospital" is any institution receiving direct or indirect payments from Medicare for graduate medical education. Reportable ownership or investment interests include those held by physicians or members of their immediate family.

Third, the statute requires reporting of payments or transfers of value worth at least $10, and transactions of less than $10 if they total $100 or more in a given calendar year. The range of items that must be reported includes cash or a cash equivalent, in-kind items or services, stock, consulting fees, compensation for services other than consulting, honoraria, gifts, entertainment, food, travel (including the destination), education, research, charitable contributions, royalties or licenses, current or prospective ownership or investment interest, speaker compensation for CME events, and grants.

CMS minimized the reporting burden where possible. Data collection and reporting requirements fall on manufacturers and GPOs, not on physicians and teaching hospitals. Physicians can voluntarily review and dispute data before public posting. For example, they could distinguish consulting fees from payments representing royalties for a product developed through their research.

The Sunshine Act is designed to provide objective information on the types of financial relationships that exist between manufacturers or GPOs and physicians or hospitals. It will allow more informed and engaged health care consumers to choose physicians using this information along with publicly available quality and resource-utilization data. The program seeks to balance the value of data transparency against its possible effects on innovation or CME. For example, information on payments related to products that are in development before regulatory approval will not be published for 4 years or until Food and Drug Administration approval has been granted, whichever comes first. In part because many CME companies have adopted comprehensive codes of conduct in recent years, CMS also worked to balance transparency with the availability of high-quality medical education by restricting reporting of CME-related payments to cases in which the manufacturer had direct influence over the choice of speaker.

Finally, this program recognizes the essential role of research payments in the development of novel diagnostics and therapeutics. A separate reporting stream for research payments will clarify for consumers that a principal investigator directing a $5 million research grant from a manufacturer is not accruing all $5 million for his or her personal use.

In the first year, data from August through December 2013 will be publicly available by September 30, 2014; subsequent reporting will be for each calendar year. Physicians will have 45 days to review and dispute any data that appear inaccurate, and manufacturers and GPOs will then be able to make necessary corrections. The data will be released online in an easily searchable form and will contain contextual information on the many appropriate reasons for which physicians and teaching hospitals maintain relationships with drug and device manufacturers.

Physicians can assist manufacturers in accurately reporting data and help to ensure that payments are correctly attributed by tracking their own payments from industry and clarifying with industry representatives what will be reported; providing companies with identifying information such as their National Provider Identifier (NPI), state licensure information, business address, and specialty; inquiring about the source of payments they receive, since transfers of value can occur indirectly — through specialty societies, for example — when funding originates with manufacturers; and participating in the prepublication review-and-dispute period to validate reported data and identify potential inaccuracies. Updating NPI information or obtaining an NPI through the National Plan and Provider Enumeration System (https://npiregistry.cms.hhs.gov) is critical.

Physicians can also supply information to manufacturers and encourage its reporting to provide the appropriate context for research funding, grants, or other payments; manufacturers may not possess this information otherwise. In particular, physician groups may want to explain how payments were obtained and divided equitably among members.

The NPPTP will improve understanding of industry–physician financial relationships. CMS is committed to working with all stakeholders to help realize its

full value and to drive further work in this critical area.

The views expressed in this article are those of the authors and do not necessarily represent the views or policies of the Centers for Medicare and Medicaid Services.

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