Socioeconomic

Letting the sunshine in: shining a new light on physician—industry relationships

Carolyn M Bruguera,1 Joshua A Hirsch2

ABSTRACT
The pending federal healthcare reform legislation includes Physician Payment Sunshine provisions that would mandate public disclosure of virtually all payments by industry to US physicians on government websites. The requirements reflect a growing trend toward public disclosure of payments following high-profile government investigations of allegedly improper payments and undisclosed conflicts of interests. The pending law would require broad disclosure and will affect most physicians. Industry and physicians groups have offered qualified support to the legislation.

INTRODUCTION
On 29 September 2009, the Boston Globe reported that two Massachusetts physicians were facing a hospital investigation of payments they received from the pharmaceutical manufacturer Eli Lilly & Co.1 The hospital had learned of the payments from the Globe, which found the information in a public report on Lilly’s corporate website. Based on the website disclosure, it appeared that the physicians may have violated hospital policy by participating in speakers’ bureaus, that is, delivering company-prepared presentations to other physicians as part of a promotional program.

This type of public disclosure may soon be required for all industry payments to US physicians. The pending federal healthcare reform legislation contains Physician Payment Sunshine provisions that would require pharmaceutical and medical device manufacturers to disclose most payments and in-kind benefits to physicians.2 Both the House and Senate versions of the legislation would mandate that the information disclosed by industry be made available to the public on a website maintained by the government.

The pending Sunshine legislation is part of a greater trend toward transparency of payments and other benefits provided by industry to physicians, hospitals and affiliated organizations. While the federal Sunshine legislation has been delayed by the larger debate regarding healthcare reform, developments since the fall of 2007 suggest that public disclosure of payments is the new norm. Healthcare providers should assume that any ‘transfer of value’ (such as payments, meals or gifts) they receive from industry will be a matter of public record.

DISCLOSURE
Physicians have long been subject to rules requiring disclosures of potential conflicts of interest in specific situations such as government-funded research, accredited continuing medical education (CME) presentations and FDA review. For example, to ensure compliance with Support of the Standards for Commercial Accreditation Council for Continuing Medical Education (ACCME) rules,3 moderators and speakers at SNIS-sponsored CME meetings are required to disclose financial relationships with industry to the meeting organizers. This information is included in the meeting program, as well as in a disclosure slide at the outset of the relevant presentation. Similarly, the SNIS requires its officers to make annual disclosures of consulting arrangements and/or equity positions in neuroendovascular or minimally invasive spine companies.

Unfortunately, disclosure rules are not always well understood and are sometimes ignored. In recent years, a number of prominent physicians have come under fire for failing to adhere to conflict-of-interest disclosure rules. In 2006, the Cleveland Plain Dealer reported that a Dr Isador Lieberman, a spinal surgeon at the Cleveland Clinic, had failed to disclose stock ownership in Kyphon, Inc., when testifying at a Medicare/Medicaid hearing regarding the benefits of kyphoplasty procedures.4 More recently, another spinal surgeon made headlines for allegedly failing to disclose payments from industry while testifying before a Senate Committee. According to news reports, Dr David Polly of the University of Minnesota testified that he was representing the American Association of Orthopedic Surgeons (AAOS) in the hearing, but was actually being paid by Medtronic, Inc. to testify.5 Following the hearing, Dr Polly’s institution received a Department of Defense grant to study the Infuse Product, and appointed Dr Polly as the study investigator. This and similar conflicts of interest were the focus of a congressional inquiry, and led to Dr Polly’s resignation from the board of the AAOS in August 2009.6 A recent study published in the New England Journal of Medicine reviewed disclosures by physicians who authored presentations at the 2008 Annual Meeting of the AAOS, as well as by members of the meeting’s organizing committee and board of directors. The study concluded that physicians disclosed only 71% of the payments covered by the meeting’s disclosure rules.7

The researchers drew this conclusion by comparing physicians’ disclosures to AAOS with the physician payment reports that are now publicly available on the websites of the five major US-based orthopedic device manufacturers. These five manufacturers (Zimmer, Stryker, Biomet, Smith & Nephew and Depuy) represent 95% of the domestic hip and knee implant market. In September 2007, all five manufacturers entered settlement agreements with the US Department of
Justice to settle allegations of improper payments to physicians. Among the novel provisions of the settlement agreements were requirements that the companies disclose on their corporate websites the names of all of their physician consultants and the payments made to them.

The *New England Journal of Medicine* study suggests that physician ethics rules may not be sufficient to ensure complete disclosure. The federal government had apparently already reached this conclusion when the orthopedic industry settlements were signed. In the same month as the settlement agreements, Senators Grassley and Kohl introduced the first version of the Physician Payments Sunshine Act in the US Senate; the original House bill followed in March 2008.

In addition to Lilly and the orthopedic manufacturers, device makers Medtronic and Edwards Life Sciences, Inc., and pharmaceutical manufacturers Merck and GlaxoSmithKline have implemented website disclosures of physician consulting payments, and Pfizer has announced it will follow suit. Several prominent medical institutions, including the Cleveland Clinic, Stanford University and Northwestern University have announced tighter restrictions on physician interactions with industry and adopted a policy of disclosing physician financial relationships with industry on their websites. In July 2009, Massachusetts and Vermont implemented laws imposing disclosure requirements similar to those contemplated by the federal bills. Similar legislation has been proposed in other states, most recently New Jersey.

If enacted, the pending Sunshine legislation will require disclosure of all ‘payments’ or other ‘transfers of value’ from pharmaceutical and medical device manufacturers to physicians. This includes cash payments (such as consulting fees and honoraria), but also covers in-kind benefits such as food, travel, entertainment and gifts. Because ‘transfer of value’ is broadly defined, the vast majority of physicians will be affected by the rules. For physicians whose practice areas involve extensive interaction with industry (including the NeuroInterventional practice), the impact is likely to be greater than for others.

The disclosure requirements will include the name and address of each recipient in a format to be prescribed by federal regulators. The information is intended to be disclosed on government websites in a searchable format, allowing patients and other members of the public to retrieve all disclosures regarding any individual physician, hospital or other ‘covered recipient.’

The details of the new law may come as a surprise to many practitioners. The thresholds for reporting payments are very low, ie, $5.00 in the House bill, $10.00 in the Senate bill. As a practical matter, physicians should assume that all meals, grants, travel and in-kind benefits will be disclosed, with the limited exceptions described in the table below. In addition, the requirements capture more than direct benefits to physicians. In both versions of the legislation, research and educational grants and charitable donations are covered; the House version also covers product samples, even where intended for free distribution to patients. To capture grants and other payments that are typically made to hospitals rather than individual physicians, the legislation includes as ‘covered recipients’ academic medical centers (in the Senate version) and all hospitals, medical schools, physician organizations and CME sponsors (in the House version).

The following chart provides an overview of the Sunshine provisions of both bills at the time of this writing. The final legislation will be determined by the conference committee harmonization process, which is expected to produce a final draft of the legislation in the next several weeks.

### Table 1

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<th>Who must disclose?</th>
<th>Senate bill</th>
<th>House bill</th>
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<tr>
<td>‘Covered recipient’</td>
<td>Physicians and academic medical centers</td>
<td>Physicians, hospitals, medical schools, all other prescribers, pharmacists, pharmacies, health insurance companies/plans, CME sponsors, physician organizations, patient advocacy groups, disease-specific groups, biomedical researchers, group purchasing organizations</td>
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| Disclosable payments | All payments and other ‘transfers of value’; includes all cash, gifts, entertainment, travel, research/education grants and equity ownership, limited exceptions below | Payments under $5, otherwise similar to Senate bill (but no exception for product samples) |

| Exceptions | Payments under $10, if aggregate value is under $100; product samples not for resale or intended for patient use, educational items for patient use, discounts, rebates | |

| First disclosures due date | 31 March 2013; must be public and searchable by 30 September 2013 | 31 March 2011, must be public and searchable by 30 September 2011 |

| Delayed reporting for payments in connection with product development agreements and clinical research | Earlier of FDA approval or 4 years from date of payment | Product development: earlier of FDA approval or 2 years from date of payment; clinical investigations: earlier of registration of trial on http://clinicaltrials.gov website or 2 years from date of payment |

| How is context defined? | Disclosures with respect to each physician must be broken down into several categories—for example consulting fees, gifts, entertainment, travel (specifying destination) | |

### Industry’s Position

Prominent industry representatives have announced qualified support for the legislation. A major condition of this support is that the statute pre-empt state requirements relating to the same disclosures, which over time could require companies to track and report different payments in different formats in all 50 states. Both bills include pre-emption, but this would not apply to the extent states impose different disclosure requirements.

Another concern raised by industry is that disclosing payments could jeopardize confidentiality of pending product development and clinical trial activities. The pending bills both attempt to address this concern by allowing for delayed reporting of payments related to these activities.

### Physician Organizations’ Perspective

Physician organizations have echoed the concerns raised by industry. The American Medical Association and the American Academy of Family Physicians both supported the 2008 version of the legislation, based in part on the promise of state law pre-emption. Both organizations have expressed concern that the 2009 legislation is too broad and allows for additional state disclosure requirements.

A significant point of concern for both physicians and industry is the lack of context required by most disclosure.
regimes. This concern was raised by AAOS President Jim Beatty following the initial disclosures pursuant to the orthopedic industry settlement agreements, and was echoed by ADVAMED in testimony regarding the Sunshine Act before the Senate Special Committee on Aging.20

In response to this concern, the Senate bill requires that disclosures identify the nature of the payment using the following categories:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel (including specified destinations)
- Education
- Research
- Charitable contributions
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or as a speaker for a medical education program
- Grants

These disclosure categories should help reviewers distinguish between different types of payment, which may alleviate concerns by physicians who contribute valuable technology or who provide multiple types of service. At the same time, the disclosures will provide insight to expenses such as travel and entertainment that have previously gone under the radar.

CONCLUSION

Public disclosure of industry payments to physicians is now becoming more widespread, largely due to government pressure following exposure of alleged improper payments and undisclosed conflicts of interest. With the Physician Payment Sunshine Act, disclosure will be mandatory for virtually all industry payments to US physicians. These disclosures will include even very small payments and in-kind benefits, as well as grants and donations. While the new law is likely to be burdensome, it is also likely to result in more complete disclosure than the current patchwork of rules and guidelines, and to increase the uniformity of those disclosures.

Regardless of one’s personal perspective, this public type of disclosure is almost certain to become law. As such, it will impact on physicians, the hospitals and societies we serve. The Neuro-Interventional discipline has historically been very technologically driven, and, will likely continue to be. As such, these federal disclosure requirements have the potential to impact Neuro-Interventionalists more than other less technologically intensive specialties. This article endeavors to increase awareness of the nuances of the current, ongoing, federal legislative efforts.

Competing interests None.

Provenance and peer review Commissioned; not externally peer reviewed.

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