Transparency and the healthcare industry: The Sun is shining

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Abstract

The demand for greater transparency in financial relationships between the healthcare industry and healthcare professionals is increasing globally, and has led to establishing government regulations and professional guidelines for detailed reporting and public disclosure of these relationships. In the US, under the Physician Payment Sunshine Act, the government requires an annual report on payments and transfers of value made by healthcare product manufacturers to physicians and teaching hospitals. The implementation rules for this act were announced in February 2013, with data collection beginning on 1 August 2013. The first reports are due to the US government by March 2014, and public disclosure of the data will begin in September 2014. Concerns are growing within the healthcare industry regarding these new transparency requirements, and the likely unintended consequences, such as reduced participation of physicians in industry-sponsored clinical trials and delays in publication of clinical trial data.

Keywords: Open Payments, Physician Payment Sunshine Act, Reporting Requirements, Transparency

For over a decade, we have seen a significant erosion of public trust in the healthcare industry. Nearly 10 years ago, in an editorial in *Circulation*, Alice Jacobs, MD, former president of the American Heart Association, noted the criticality of rebuilding public trust in medicine.[1] Her commentary raised issues related to financial conflicts of interest in medical research and medical publications, and raised the question 'whether individuals with relationships with industry, arguably often the most knowledgeable experts in a field, should be allowed to participate in the writing of scientific statements and guidelines'.[1] Today, nearly 10 years later, some of the same concerns continue to be heard.[2]

On the positive side, steps have been taken towards restoration of public trust, especially with respect to the reporting of data from industry-sponsored clinical studies and the role of professional medical writers.[3–6] The International Society for Medical Publication Professionals (ISMPP) introduced a certification program, based in large part on the ethics of developing medical publications and disseminating clinical trial data.[7] Manufacturers of drugs and medical devices have taken important steps to broaden transparency around clinical trials information.[8–10] Government-mandated transparency laws or self-policing guidelines or policies exist in several countries such as Australia, Denmark, France, Japan, Portugal, Slovakia, The Netherlands, and the United Kingdom. In the US, individual state legislation has been in effect since 1993, and US Federal legislation, known as the US Physician Payment Sunshine Act, was passed in 2010 (Figure 1).

The Sunshine Act: An overview

In March 2010, the Patient Protection and Affordable Care Act, popularly called Obamacare, was signed into US law. It includes the Physician Payment Sunshine Act (Sunshine Act), which is formally called the National Physician Payment Transparency Program: Open Payments.[11]

The Sunshine Act arose out of activities related to enforcement of the US federal anti-kickback statute involving financial relationships between the healthcare industry and healthcare professionals (HCPs).[12] The act is based on the belief that if financial relationships between industry and HCPs were made public, it would help government enforcement and curb such activities. The law established

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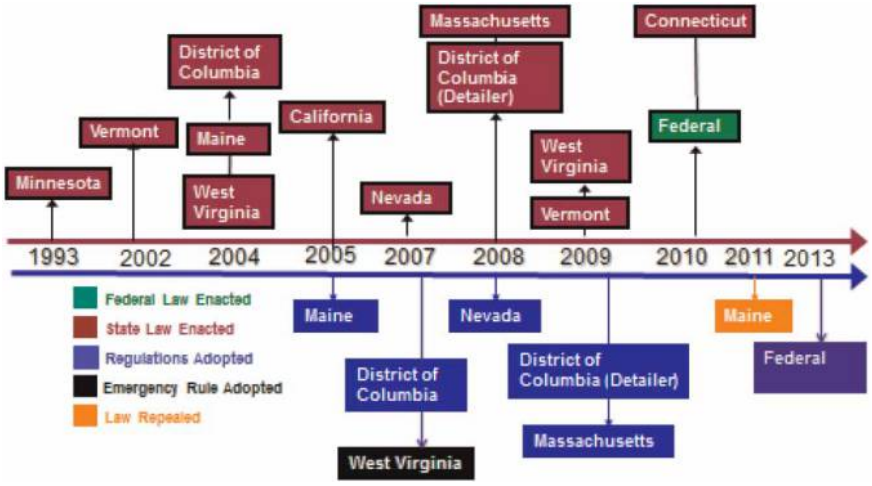

Figure 1: Laws enacted to increase transparency in industry–healthcare provider (HCP) relationships. Reproduced with permission, Porzio, Bromberg & Newman, P.C., Morristown, NJ, USA.

legal requirements for the reporting of certain financial transactions (payments or transfers of values [TOV] ≥ US$10) between manufacturers of healthcare products that are covered by the US government Medicare, Medicaid, or Children's Health Insurance Programs (applicable manufacturers [AMs]) and physicians who carry a US licence to practise medicine (covered recipients [CRs]). It also applies to teaching hospitals and group purchasing organisations (Table 1).[13]

The law required that AMs begin data collection on 1 August 2013, and report data for calendar year 2013 (1 August to 31 December) to the Centers for Medicare and Medicaid Services (CMS) on 31 March 2014. The physicians themselves do not have to report the data. CMS is required to publish aggregate data on a public website by September 2014, and each year thereafter (Figure 2).[13] The reporting categories include, among others, consulting fees, honoraria, compensation for participation in research or education, grants, charitable contributions, royalties, current or prospective ownership or investment interest, gifts, entertainment, travel and lodging, and food and beverages.[13] A summary of the Sunshine Act directed towards healthcare practitioners was recently published in the *New England Journal of Medicine*.[14]

Failure to adhere to the reporting requirements of the Sunshine Act is associated with significant financial penalties. Unintentional failure to submit data has a penalty of at least $1,000 but no more than $10,000 for each payment or other TOV, or ownership or investment interest not reported as required, with an annual maximum of $150,000. Penalties for intentional failure to submit are even higher.[13]

Exemptions and exclusions

The rules for implementation list a number of exemptions from and exclusions to the reporting

Table 1: Definitions of applicable manufacturers, covered products, and covered recipients under the Sunshine Act (CMS Rules 2013).[13]

Applicable manufacturers	Covered products	Covered recipients
Any manufacturer, foreign or not, which operates in the US (including by selling a product) must comply with the reporting requirements, regardless of where the product is physically manufactured	Any drug, device, biologic, or medical supply, that is reimbursable by Federal government (Medicare, Medicaid, or Childrens' Health Insurance Program)	Physicians (MD, DO, DPM, OD, DCh) holding a US licence to practise medicine
Entities based outside of the US that have operations in the US are subject to these reporting requirements	Excludes OTC	Teaching hospitals (CMS to provide list annually)
Joint ventures/co-promotions requires reporting by the applicable manufacturer that actually made the payment or other transfer of value (unless decided by the parties to report differently) and that the payment or transfer of value be reported once	Devices and medical supplies limited to those that, by law, require premarket approval by or notification to the FDA	Group purchasing organization that purchases, arranges for or negotiates purchase of covered drug, device, biological, or medical supply, operating in the US, or in a territory, commonwealth or possession of the US

Figure 2: Timeline for Sunshine Act reporting. CMS, Centers for Medicare, and Medicaid Services.

requirements. For example, physicians who are employees of AMs are exempt. The exclusions include, but are not limited to, indirect payments or other TOV where the AM does not know the identity of the CR; payments or other TOV less than $10 unless the aggregate amount exceeds $100 in a single calendar year; product samples; and educational materials and items that directly benefit patients. The full listing of exclusions can be found on the CMS website.[13]

The Sunshine Act and medical publications

The Sunshine Act implementation rules mention but do not provide clarity on support provided to CRs for the development of industry-sponsored medical publications. To help address the questions surrounding this issue, ISMPP has recently released the 'ISMPP Suggested Approaches for Sunshine Act Interpretation and Implementation for Publication Support Requirements'.[15] Based on research and meetings with various stakeholders from industry and CMS, the Task Force concluded that '…provision of publications support is a TOV to CRs who are authors on medical publications'.[15] This is believed to be the case for publications that are included in research contracts and for those that are not (e.g. review articles). For the purpose of medical publications, ISMPP's suggested definition of the TOV is 'any support provided to CR authors for any publication that will be submitted, or is intended to be submitted, to a scientific or medical journal, or provided to authors/speakers for submission to or presentation at a professional congress'.[15] As ISMPP understands, a TOV is not reportable if the authors of publications are employees of the AM that provided the support; by extension, this may also include authors who are employees of medical writing agencies or freelance medical writers that are paid by AMs.

ISMPP has suggested two alternatives for consideration in determining the value to be assigned to publication support for authors who are CRs.[15] The first is on a project-by-project basis, where one would divide the total cost of the publication support by the number of authors associated with the publication. To do this, actual costs are assessed, divided by the total number of authors, and assigned to each external CR; internal/company, and ex-US authors are included in the calculation but have no reportable TOV. The second is to determine the fair market value (FMV) of publication support that CRs would receive across various publication types (e.g. abstract, manuscript, poster) using a sum of average costs associated with the type of publication divided by the average number of authors on that publication type. Each AM would determine a representative sample size upon which to base the FMV calculation.

Because of the complexity of the issue, and the various scenarios that could occur across different manuscripts, ISMPP did not issue a prescriptive algorithm for determining the value of the support provided to CRs.

Transparency, global legislation, and policies

As mentioned previously, transparency is an important issue that is impacting global legislation and policies. For example, in May 2013, France passed a version of the Sunshine Act requiring pharmaceutical companies to make public the gifts provided to HCPs, and Denmark has required that companies declare payments to physicians for almost 5 years. Critics, however, argue that there are shortcomings to both these legislations that prevent full transparency. There are no equivalent disclosure requirements in other countries within the European Union. In Australia, the Netherlands, and Japan, reporting is voluntary and is being led by industry associations. Adoption of a reporting model similar to the US Sunshine Act will likely be difficult because of the differences in the healthcare systems across various countries.

It is worthy to note, however, that some additional efforts are being made by foreign trade associations in the global push for transparency around relationships between the pharmaceutical industry and HCPs. For example, the industry association of the medicinal products sector of the Association of the British Pharmaceutical Industry (ABPI), which already requires its members to disclose numerous areas of interactions with medical practitioners, recently amended its rules on interactions with HCPs and patient organisations. All 180 members of the ABPI are required to comply with the ABPI Code of Practice for the Pharmaceutical Industry. In addition, the European Federation of Pharmaceutical Industries

and Associations now requires its members to publicly disclose any direct or indirect financial support provided to patient organisations.

There are a number of arguments for and against global implementation of laws similar to the US Sunshine Act. Proponents argue that implementation of a global transparency system would assist companies in developing a comprehensive system across all its business units, in effect including both US and foreign medical professionals. They also state that these activities may improve a company's overall compliance, thereby decreasing the need for enforcement activities over time.

On the negative side is the potential large cost associated with implementing such systems. Companies must develop and maintain data collection processes and systems that will need to be adjusted to conform to the CMS rules. Collecting and reporting such a huge amount of information, especially in the absence of clear CMS guidelines on how spend data should be identified and categorised, will require significant time and dedicated personnel. This would be even more difficult to manage globally given the various and ever-changing standards evolving in different countries around the world.

Impact on healthcare providers: Are unintended consequences looming?

Whether or not the Sunshine Act will have unintended consequences with respect to relationships between physicians and industry remains to be seen. However, there are concerns over the requirements set forth in CMS rules. One concern is that information available publicly might unfairly distort the positive aspects of physicians–industry relationships. Most TOV involve FMV payments in exchange for consulting, education, and research. However, according to John Kamp, Executive Director for the Coalition for Healthcare Communication, the CMS database 'will be a huge target for critics of industry, the press, and plaintiff attorneys seeking to sue industry or doctors'.[16] The dangers of this are all the more disconcerting given serious questions regarding the accuracy of the database that may cause reporting errors.

According to a study conducted by Industry Standard Research, physicians are worried about the impact the Sunshine Act will have on their practice.[17] Of 103 physician respondents, 74% said they were not in favour of sharing these data. If physicians are concerned that interacting with the pharmaceutical industry has a negative connotation, these relationships, which are vital to the public health, could be put at risk.

Limitations on authorship

One particularly growing concern is how authors of industry-sponsored publications may react to reported TOVs for editorial or writing assistance provided by medical communications agencies. This assistance is generally considered important in maintaining quality, accuracy, and timeliness of articles submitted to peer-reviewed journals. It is an accepted practice, provided the nature and funding of the support is fully transparent.

Initial reports indicate that many physicians were not aware that this type of TOV is reportable and are concerned regarding how much TOV will be allocated to an individual physician based on provision of medical publications support. As such, some physicians are beginning to ask that their names be removed from industry-sponsored papers and indicate that they will be less likely to author such publications in the future.

This comes at a time when the *BMJ* has called for legislation in Europe (i.e. a European Sunshine Act) requiring drug companies to declare whom they pay and how much.[18] Additionally, the American Society of Clinical Oncology has taken the issue of transparency to another level by issuing a new conflict of interest policy reflecting a commitment to transparency and independence in the development and presentation of scientific and educational content.[19] The new policy focuses on financial interactions with industry and goes beyond disclosure by imposing restrictions on authors who work for, hold stock in, or participate as a speaker for a pharmaceutical company.

While it is unclear if this kind of punitive approach to forcing transparency around these important physician–industry collaborations will be copied by other journals, many are concerned that such actions will come at a high cost to companies' abilities to report the results of important clinical trials to physicians and patients.

Conclusion

Full transparency in financial relationships between the healthcare industry and HCPs can be a good thing. The goals for transparency are laudable; no doubt we all share the desire to support unbiased and medically sound healthcare practices that are not influenced by financial relationships. At times, legislation developed to enforce transparency can have unintended consequences. For example, will we see a hesitance on the part of clinical investigators to work with industry due to concern for potential misinterpretation of their publicly available financial relationship data? Might this translate

into delays in the publication of industry-sponsored clinical trial results because busy clinicians decide to forgo medical writing support? And finally, will these changes have an impact on medical writers? It remains to be seen whether this, or any other unintended consequences, occur.

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