PHYSICIAN PAYMENT SUNSHINE ACT: POTENTIAL IMPLICATIONS FOR MEDICAL PUBLICATION PROFESSIONALS*

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The Physician Payment Sunshine Act (Sunshine Act) was passed in 2010 by the US Congress as part of the Patient Protection and Affordable Care Act (PPACA; known more commonly as the Affordable Care Act).[1] The Sunshine Act contains important changes to the law that may affect how medical publication professionals conduct business. The areas that may be affected include the following:

- Relationships with clinical trial investigators and authors
- Scope of information to be tracked, recorded, and managed
- Compliance regulations

The Sunshine Act arose out of activities related to enforcement of the US federal anti-kickback statute involving financial relationships between health care industry (pharmaceutical, biologics, and device) companies and health care providers. Its passage reflects the ever-increasing trend toward requirements of greater transparency in industry-physician interactions. The Sunshine Act is based on the belief that if financial relationships between industry and physicians are made publicly available, not only would this aid government enforcement, but it would also help to curb such activities.

On December 14, 2011, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule interpreting the Sunshine Act.[2] In the proposed regulations, CMS sought to clarify parts of the Sunshine Act that were ambiguous or unclear in the statutory language itself. In addition, CMS provided instructions for companies attempting to comply with the Sunshine Act's reporting requirements.

The Sunshine Act requires "any applicable manufacturer that provides a payment or other transfer of value to report certain information to the Center for Medicare and Medicaid Services (CMS), part of the US Department of Health and Human Services (DHHS), regarding those payments and other transfers of value."[1] With the initial report to be filed by March 31, 2013, the initial collection period for the reporting is expected to begin sometime in 2012, with the exact date for initiation of data collection dependent on when the final regulations are issued.[2] The information is expected to be made publicly available starting September 30, 2013.

WHAT IS THE PHYSICIAN PAYMENT SUNSHINE ACT?

As noted, the Sunshine Act is a section within the PPACA that requires reporting of all financial transactions and transfers of value between manufacturers of pharmaceutical/biologic products or medical devices and physicians, hospitals, and covered recipients (Table 1).[1] The Sunshine Act applies to all companies that manufacture products that are reimbursed by the US federal government; however, in considering how and what to report, it may be prudent to track information on products that are not currently reimbursed, as they may become so in the future. This precaution will alleviate the need to reconstruct the past, should the product become eligible for federal reimbursement.

WHAT ARE THE REPORTING REQUIREMENTS?

Reporting is required to begin March 31, 2013, for information collected in 2012, and will continue for each full calendar year thereafter. The Sunshine Act requires CMS to establish a Web site to host the aggregated information in a publicly available, electronic, searchable database; the reported data must be clear, understandable, eas-

Table 1. Who Is—and Isn't—Covered Under the Sunshine Act[1]

Applicable manufacturers	Any company "engaged in the production, preparation, propagation, compounding or conversion" of a "drug, device, biological, or medical supply" for which payment is available under Medicare, Medicaid, or a state children's health insurance program
Covered recipients	Physicians and teaching hospitals, except physicians who are employees of the manufacturer Any entity that receives monies from a manufacturer at the request of a covered recipient; eg, grant request to institution or contribution to charity
Not included	Health care professionals who hold degrees and licenses and provide clinical services other than MDs and DOs, such as PhDs, RNs, LPNs, PAs

**This article is intended to provide an overview of what the authors know as of January 31, 2012, about the Sunshine Act and how it might affect the medical publication profession. It is provided as an informational summary and is in no way intended to provide legal advice from the authors or represent the views of their employers.*

ily aggregated, and downloadable. In addition to financial information, the database will also include background on relationship(s) between manufacturers and physicians; information about physicians' ownership interest or investment relationships with the manufacturer, not only for the physician but also for immediate family (eg, spouse, child, sibling); and any enforcement actions that have been taken for noncompliance. The database will be administered by CMS.

Several minimum reporting requirements and exclusions are covered in the Sunshine Act (Table 2).[1,2] The Proposed Regulations require that manufacturers report the following for each transfer of value:

1. Covered recipient's name, address, and national provider identifiers[3]
2. Amount of payment or transfer of value
3. Date of payment
   For payments made over multiple dates, such as a consulting agreement, manufacturers may report the total payment on the first date or may use separate line items for each payment.
4. Associated covered drug, device, biologic, or medical supply
   If the payment is reasonably associated with one drug or device, it must be reported.
5. Form of payment
   Manufacturers must select one of the following: Cash/Cash Equivalent, In-Kind Items or Services, Stocks/Stock Options/Ownership/Dividends/ROIs, Other
6. Nature of payment
   Manufacturers must select one of the following: Consulting Fees, Compensation for Services other than Consulting, Honoraria, Gift, Entertainment, Food, Travel (including destinations), Education, Research, Charitable Contribution, Royalty or License, Ownership/Investment Interest, Compensation for Faculty or Speaker at Medical Education Event, Grant, Other

Table 2. Sunshine Act Reporting Requirements[1,2]

Included	Excluded
Generally, anything of value provided to a covered recipient • Fees for service, honoraria, food, travel, educational items, research, charitable contributions, grants, royalties or licenses, etc.	Certain items are excluded from reporting, including • Payments under $10, unless the aggregate amount paid to a covered recipient exceeds $100 per year • Product samples and educational materials for the benefit of patients • Loan of a covered device for a trial period ≤ 90 days • In-kind items provided for use in charity care • Items or services provided under a warranty • Discounts (including rebates) • A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund • In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan • In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional • A transfer of anything of value to a physician if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding • Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient

CMS clarified that manufacturers must report a single form of payment and nature of payment for each transfer of value made.[2] For example, if a physician received meals and travel in association with a consulting fee, CMS will require that each segregable payment is reported separately in the appropriate category. The applicable manufacturer would have to report three separate line items: one for consulting fees, one for meals, and one for travel. The amount of the payment would be based on the amount of the consulting fee and the payments for the meals and travel. For these lump-sum payments or other transfers of value, CMS clarified that the applicable manufacturer must break out the disparate aspects of the payment that fall into multiple categories for both form of payment and nature of payment.

The area of most concern for members of the medical publication profession is the lack of definition of "transfer of value" in bullet point 2. Although not specifically listed, fully disclosed medical writing and editorial support provided by an "applicable manufacturer" (eg, pharmaceutical company) to an MD or DO is considered transfer of value. If as expected, an applicable manufacturer pays medical publication professionals acting as its agent to provide support to MDs or DOs, the value of those services is a "transfer of value" to the MD or DO. Accordingly, we anticipate that medical writers and publications and communications companies will need to provide data to their clients for reporting. This will also apply to manufacturers with staff who perform these functions.

As we have experienced with the passage of other acts that affect the medical publication profession,

requirements may be refined or modified as details of the implementation are further delineated.

Failure to comply with the Sunshine Act is not without penalty. Manufacturers who fail to comply will be fined $1,000-$100,000 per missing payment, depending on the circumstances. Fines will be capped at $1,000,000 per company per year.[1]

HOW DOES THE SUNSHINE ACT RELATE TO STATE LAWS ON TRANSPARENCY IN INDUSTRY-PHYSICIAN RELATIONS?

Details on individual state laws that mandate disclosure of industry-physician relationships, from disclosing specific information to bans on certain types of activities, are beyond the scope of this article. Of note, however, is that the Sunshine Act preempts state laws only if they are **less** restrictive than the Sunshine Act; state laws that are **more** restrictive may still require "applicable manufacturers" to provide additional information not included in the Sunshine Act.

HOW WILL FAIR MARKET VALUE OF PROFESSIONAL MEDICAL WRITING AND PUBLICATIONS SUPPORT BE DETERMINED?

The most critical question for all medical publication professionals is how to determine the value of the medical writing support to authors; how do we determine the financial worth of that transfer of value? How do we determine the value to each author on articles with multiple authors, some of whom may be sponsor-authors? As this is charting new territory, there are currently no hard and fast, standardized, financial models available to medical publication professionals.

In attempting to answer these questions, it is important to consider independent objective market data. Some organizations may decide to look to outside valuation consultants for data gathering and/or formal valuation opinion. Professional societies may also provide support. For example, the International Society for Medical Publication Professionals has convened a Sunshine Act Task Force to undertake research and provide guidance to their membership.

Medical writers and medical publication companies should work with their clients to identify needs and develop reporting systems that will capture the data required by manufacturers. Each manufacturer must independently determine fair market value, and the ideal would be to develop a standardized approach for such determination. The bottom line is that medical publication professionals must develop a reasonable way to value the medical writing and publications support provided to physicians that is justifiable and based on objective data.

Note: *See page 24 for information about the effect of the Sunshine Act on continuing medical education.*

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Image Manipulation

Image manipulation is an important ethical issue for scientific journals. You can gain a better understanding of this issue through two online resources.

Visit the International Society of Managing and Technical Editors Web site to listen to an interview with Liz Williams, PhD, Executive Editor of *The Journal Cell Biology* (**http://tinyurl.com/76nvto4**). Dr Williams discusses the evolution of image alterations in the scientific literature, the images most vulnerable to manipulation, the tools necessary to detect image manipulation, and the importance of having an image manipulation policy. Also included are links to additional resources on image manipulation.

Visit the Council of Science Editors (CSE) Web site (www.councilscienceeditors.org) to review three presentations on image integrity from the 2011 CSE annual meeting.

ETHICS INFO