The Sunshine Act: Shining Light on Impending Implementation ***Katherine L. Kraschel\*****Foley & Lardner LLP Boston, MA* ***Brendan Abel*** *Office for Interactions with Industry* *Partners HealthCare Boston, MA* <http://www.healthlawyers.org/Members/PracticeGroups/IHC/Documents/IHC_March14.pdf>

**T**he Physician Payments Sunshine Act (Sunshine Act or Act) is a rarely cited component of the Affordable Care Act(ACA). The Sunshine Act increases the transparency of payments and other transfers of value from manufacturers or group purchasing organizations (GPOs) of pharmaceuticals and medical devices to physicians and hospitals. With the first annual reporting deadline for manufacturers approaching on March 31, and the launch of a resulting public, searchable website, entitled Open Payments, listing details of payments to individual physicians slated for September, this provision of the law will attract the attention of affected parties such as manufacturers, physicians, and hospitals as well as third parties such as the media and health care consumers.

History

Disclosure of financial interests is not a new concept within the medical community. The Cleveland Clinic, for example, has required the posting of certain information regarding their physicians’ ties with industry on its website since 2007.1 Several states, including Massachusetts, Minnesota, and Vermont, have passed legislation requiring public reporting of certain information about payments made to physicians.2 At least 13 pharmaceutical companies are now required to publicly post information about payments they make to physicians as conditions of corporate integrity agreements.3 Lastly, many industry and medical professional societies require disclosure of certain financial interests either publicly or in relevant situations (i.e., presentations, journal publications, advisory boards, etc.). Never before, though, have financial disclosure requirements come from the federal government to the biomedical community, and rarely have

disclosure requirements, regardless of source, been as expansive as those contained in the Sunshine Act.

The ACA provided the perfect avenue through which to pass the Act which includes a myriad of components added by individual legislators during the chaotic drafting and negotiating of the bill. The resistance in the path towards passage was not surprising given the large number of financial relationships that potentially require disclosure and thus create an administrative burden for manufacturers and GPOs.

In a large-scale survey in 2007 of more than 3,000 physicians across six specialties, 94% of physicians reported some type of relationship with industry, while 18% reported receiving compensation for consulting.4 A substantial portion of the biomedical community will be affected by the law, leading physicians, hospitals, and manufacturers to pay close attention to the regulations that operationalize the law as they have emerged.

The Centers for Medicare & Medicaid Services (CMS) issued proposed regulations in December 2011 and requested commentary from all interested parties.5 In February 2013 CMS issued final regulations that require reporting of payments or transfers of value from all pharmaceutical and medical device manufacturers and GPOs to physicians or teaching hospitals (covered recipients) occurring on or after August 1, 2013 for calendar year 2013.6 Reports for the shortened August-December 2013 calendar year must be submitted by manufacturers and GPOs electronically to CMS by March 31, 2014 and will be due on the 90th day of each year for the subsequent calendar year.

Types of Payments Reported

Payment or transfer of value is defined broadly with a low threshold of $10, and thus will include a vast array of funds

transferred from covered recipients. However, reporting only applies to payment from entities that manufacture at least one covered product that includes any drug, device, biological, or medical supply covered under Medicare, Medicaid, or the Children’s Health Insurance Program.7

In addition to payments made directly from manufacturers, indirect payments or transfers of value must be reported. These indirect payments are defined as payments or transfers in which the manufacturer “requires, instructs, directs, or otherwise causes the third party” to pay or transfer value to a covered recipient. There is no knowledge requirement that triggers reporting of these third-party payments. If a manufacturer is not aware of the identity of the covered recipient, a payment made by a third party will be imputed back to the manufacturer and must be reported. Food and beverage values of $10 or more must be disclosed as well as values of less than $10 when the aggregate annual amount transferred to the covered recipient exceeds $100. In reporting food and beverage values, manufacturers must determine and report the value per person by dividing the entire cost of food and beverage by the number of individuals who partake in a meal (including individuals who are non-covered recipients). However, meals, snacks, soft drinks, or coffee that a manufacturer provides and are generally available to all participants at a large conference or similar events need not be reported.8

The breadth of the Sunshine Act is exemplified by the inclusion of “research” as a category of reportable payments. The regulations require disclosure of all transfers of value for research, from basic and applied research through product development (or, in other terms, preclinical through Phase IV research).9 Research-related payments are reportable whether made directly or indirectly to a covered recipient, and the research only needs to be subject to a written agreement or contract or a research protocol. Of note, the Open Payments website will treat research payments differently by listing them separately on the website, and by including additional information such as the name of the research study, the covered products subject to the study, and at the manufacturer’s option, the ClinicalTrials.gov identifier. These measures are taken to address concerns regarding the appearance of substantial payments to investigators who are performing sponsored research and to mitigate confusion that such research payments are akin to other reportable payments on the Open Payments website. For sponsored research agreements, the entire sum of research support will be attributed as a payment to an individual physician who is the principal investigator, even though all or most of the money will be used to fund the research overhead, salaries for research staff, subcontracts to third parties, institutional review board fees, etc.10 Many times, the researcher listed as receiving substantial support from a manufacturer will, in fact, receive no salary support or increase for such arrangements.11 The regulations contain a notable provision to offer market protection of certain research that is in development but has not yet reached regulatory approval: disclosure of such research payments can be delayed until the earlier of four years from the date of transfer or U.S. Food and Drug Administration (FDA) approval of the product to protect the companies’ proprietary interests.

Definition of Manufacturer

Under the Act, all pharmaceutical and device manufacturers and GPOs are required to register with CMS within 90 days of the end of the calendar year in which payments are to be reported.12 There are two categories of manufacturers as defined by the regulations. The first category includes entities engaged in the production, preparation, propagation, compounding, or conversion of a covered product. It does not include distributors or wholesalers that do not hold title to any covered product or entities that produce covered product solely for use by or within the entity or by the entity’s own patients. Manufacturers that do not produce a covered product or do so only under a written agreement for another entity and do not hold FDA approval, license, or clearance are only required to report payments related to covered products. In addition, manufacturers whose total gross revenues from covered products constitute less than 10% of its total gross revenue are not required to report payments that are related to covered products. …

Appeals Procedure

Once manufacturers or GPOs report payments, a review and resolution period will begin at least 60 days before the information is made public to allow for a two-phase review and dispute resolution process to occur. Covered recipients may register with CMS to receive notification regarding the review process and are otherwise notified using an online posting and upon reviewing the information reported about the covered recipient, if the information is correct, the covered recipient may electronically certify the information reported is accurate. If the covered recipient disagrees with information reported, the covered recipient may initiate a dispute any time once the 45-day review process has begun and before the end of the calendar year. ...

Penalties

A manufacturer’s or GPO’s failure to report is subject to a civil monetary penalty (CMP) of not less than $1,000 but not more than $10,000 for each payment or transfer of value not reported in a timely, accurate, or complete manner as required under the regulations. The aggregate CMP that can be imposed on each manufacturer or GPO in a given annual reporting period may not exceed $150,000. If a manufacturer or GPO *knowingly* fails to report, the maximum annual CMP is $1 million.13

Considerations as Reporting Deadline and Open Payments Site Launch Approach

While hospitals and physicians do not have an affirmative duty to report information under the Sunshine Act, one question they face is how proactive to be in accessing information reported by manufacturers and GPOs. By registering with CMS to receive notice of all their applicable payments and transfers and monitoring Open Payments regarding affiliated physicians, hospitals can prepare for and anticipate inquiries about reported payments to the hospital and its physicians and use the information as a cross-check for other reporting obligations. The new source of information will give institutions with public health service funding a method to uncover possibly omitted “significant financial interests” that are required to be reported by certain researchers under the research conflict of- interest regulations.14 …

From a public relations perspective, close cooperation and strategic planning with communications offices in the weeks leading up to the Open Payments launch are advisable to prepare for responses to press and patient inquiries, particularly when there is a large amount of funding or compensation reported or a prominent researcher involved. In addition, hospitals privy to information prior to its release on Open Payments will be prepared to respond to requests for clarification about discrepancies of reported payments across disclosure sources. For example, a physician in Massachusetts could have one set of disclosures listed on the Open Payments website, while only a portion of those payments are reported on a state repository because of conflicting inclusion criteria or date ranges. Meanwhile, a journal publication by the same physician could list yet other disclosures, such as expert witness compensation or equity in a basic science start-up, that are not contained on state or federal websites, or it could list substantially higher payment amounts because of aggregation over two or three years. Finally, the food and beverage reporting requirement as created its own bevy of confusion and administrative burdens. Substantial ambiguity remains regarding the threshold of how many attendees it takes to constitute a “large conference” that does not require food-related reporting for buffet meals, and confusion about when there are “identified” recipients, and to what extent manufacturers can require hospitals to track names of such recipients. …

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1-R. Steinbrook, *Online Disclosure of Physician-Industry Relationships,* 360 New Eng. J. Med. 325, 325 (2009).

2 -American Med. Ass’n, State “Sunshine” Laws, *available at* <https://www.ama-assn.org/sites/default/files/media-browser/specialty%20group/washington/sunshine-act-brochure.pdf>

3- S. Agrawal, N. Brennan, and P. Budetti, *The Sunshine Act—Effects on Physicians*, 368 New Eng. J. Med. 2054, 2055 (2013).

4- Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D., *A national survey of physician-industry relationships,* New Eng. J. Med. 2007;356:1742-1750 (Of note, many of these “relationships” would not be subject to disclosure under the Sunshine Act: many relationships consisted of receiving food in the workplace that could beunder the *de minimis,* and many reported receiving drugs samples, which is generally excluded in the law.).

5- 76 Fed. Reg. 78742-78773 to be codified at 42 C.F.R. pts. 402 and 403.

6- 78 Fed. Reg. 9458 to be codified at 42 C.F.R. pts. 402, 403.

7- CMS requires payments to be reported in one of 14 categories: charitable contributions, consulting fees, compensation for non-consulting services, current or prospective ownership or investment interests, direct compensation for speaker or faculty for medical education programs, education, entertainment, food and beverages, gifts, grants, honoraria, research, royalty or licenses, or travel and lodging.

8- The law requires manufacturers to provide the names of the recipients of food, though CMS recently clarified that disclosure of specific recipients is not required when it would be difficult to identify who exactly consumed the food and beverage.

9- Research is defined as “a systematic investigation designed to develop or contribute to generalized knowledge relating to public health, including behavioral or social sciences research. This term encompasses basic and applied research and product development.” Centers for Medicare & Medicaid Services. Medicare, Medicaid, Children’s Health Insurance Programs: transparency reports and reporting of physician ownership or investment interests.

10- *See* Gary Shangold and Michael Koren, *Impact of the Sunshine Law ‘Open Payment’ Provision on Clinical Research,* 12 MRLR 828 (2013).

11- *Id.*

12- As of the date of submission, CMS has not yet opened registration for manufacturers and has changed the date of registration opening from January 1, 2013 to “early 2014.”

13- Factors used in determining the amount of CMP imposed include: the length of time the manufacturer or GPO failed to report, including the amount of time the manufacturer or GPO knew of the payments or transfer of value that should be reported; the amount of payment the manufacturer or GPO failed to report; the level of culpability of the manufacturer or GPO; the nature and amount of information reported in error; and the degree of diligence exercised in correcting information reported in error.

14 42 C.F.R. pt. 50, subpt. F; 42 C.F.R. pt. 94