Analysis

The Payment Sunshine Act: Assessing the Compliance Risks for Healthcare Providers

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National healthcare reform legislation adopted in March 2010 significantly expanded the compliance risks for healthcare providers.[1] Among other policy changes with a major impact for suppliers of healthcare products and services, the legislation mandated transparency in the financial relationship of medical supply companies to teaching hospitals and physicians. Specifically, Section 6002 of the legislation (the Sunshine Law) requires pharmaceutical, device, biological, and other medical supply companies whose products are paid for by public healthcare programs, such as Medicare and Medicaid, (hereinafter Covered Manufacturers) to report payments and other transfers of value (Payments) they provide to physicians and teaching hospitals for a wide array of purposes, including consulting, speaking engagements, advisory board service, travel, food, royalty payments, and clinical research.[2] While the Sunshine Law places the burden on Covered Manufacturers to disclose to the Department of Health and Human Services (HHS) information about the Payments, access to the information by prosecutors and the press has significant compliance implications for healthcare providers.

To date, industry payments to physicians have been disclosed under state sunshine laws and Corporate Integrity Agreements (CIAs) between prosecutors and pharmaceutical and device companies. As a result, numerous pharmaceutical companies already disclose payments to physicians on publicly accessible websites as do five large manufacturers of orthopedic devices.[3] Disclosure of physician payments has generated extensive press and regulatory scrutiny for both physicians and their affiliated institutions. In particular, attention has centered on the conflicts of interest that industry payments can pose to physicians with regard to treatment, research, and medical scholarship.[4] No information has been disclosed about payments to teaching hospitals to date, but like disclosure of payments to physicians, this information is likely to garner significant public attention.

Press coverage and federal prosecutions of pharmaceutical and device manufacturers suggest the extent of Payments to physicians for a broad array of purposes, including royalty payments, consulting, speaking engagements, advisory boards, and research. Recent congressional investigations also have highlighted conflicts of interest in clinical research. Prominent universities, including Emory and the University of Cincinnati, have faced regulatory scrutiny in the aftermath of failure by researchers to report their conflicts to the university so it could manage the conflicts as required by federal regulations.[5]

Survey studies of physicians also underscore the extensive financial relationship between industry and department chairs in academic medicine, a group sought out by pharmaceutical and device companies as "key opinion leaders." In one national study, almost two thirds of department chairs had some kind of financial relationship with industry; 27% served as a consultant, 27% served on a scientific advisory board, 14% were paid as speakers, 7% as an officer, and 11% as a member of the board of directors of a pharmaceutical, device, or other medical supply company.[6]

Public disclosure of the Payment information will create a powerful new tool for prosecutors regarding potential overuse or misuse of federal and state healthcare funds.[7] Physicians, hospitals, and other healthcare providers therefore should prepare for the public scrutiny likely to follow implementation of the Sunshine Law. This article discusses the Sunshine Law requirements, the risks posed by disclosure, and the steps that providers can take to prepare for public access to information about Payments by Covered Manufacturers to physicians and teaching hospitals.

Mandatory Disclosure Under the Sunshine Act

Under the Sunshine Law, by March 31, 2013, and on the 90th day of each calendar year thereafter, Covered Manufacturers must submit to the HHS Secretary information about Payments made to physicians and teaching hospitals throughout the preceding year.[8] Payments made starting in January 2012 must be disclosed by HHS on a public website on or before September 30, 2013, and on June 30 of each year thereafter. HHS is charged to present the information in a format that is easily aggregated and searchable by manufacturer and by physician and hospital recipient.

Mandatory Public Reporting of Payments and Gifts

Pursuant to the Sunshine Law, Covered Manufacturers must report to HHS any Payment made to a physician or teaching hospital, including detailed information about the nature and value of remuneration provided. Specifically, a Covered Manufacturer must report: (1) the name and business address of the physician or teaching hospital to which the Payment was made; (2) the physician's specialty and National Provider Identifier; (3) the amount and date(s) of the Payment; (4) a description of the form of the Payment (i.e., cash, in-kind items or

services, stock, stock option or any other ownership interest, dividend, profit, or return on investment); (5) a description of the nature of the Payment (i.e., consulting fee, honoraria, gift, entertainment, food, travel (including the specified destination), education, research, charitable contribution, 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, or grant); and (6) the name of the product, if the Payment is related to marketing, education, or research specific to a drug, device, biological, or medical supply.[9] HHS has the authority to mandate reporting of additional information regarding covered Payments.

The Sunshine Law provides some exceptions to public reporting, including:

- a transfer of anything of value less than $10, unless the aggregated amount transferred by the Covered Manufacturer to the physician or teaching hospital exceeds $100 annually;
- product samples intended for patient use;
- patient educational materials that directly benefit patients;
- the loan of a device for a trial period not to exceed 90 days for the purpose of evaluating the device;
- items or services provided under a contractual warranty, where the terms of the warranty are set forth in the purchase or lease agreement; and
- discounts, including rebates.

In a provision that seeks to balance disclosure with the interests of Covered Manufacturers in proprietary, confidential information, the Sunshine Law provides that remuneration for product development and research with respect to a potential new medical technology, drug, device, biological, or medical supply, or new application of such product, shall not be disclosed by HHS to the public until the Food and Drug Administration approves the product, or four calendar years after the date such payment or transfer is made, whichever is earlier.

Reporting of Physicians' Investment Interests

In addition to mandatory reporting by Covered Manufacturers of Payments to a physician or teaching hospital, Covered Manufacturers and group purchasing organizations must report any ownership or investment interest, other than interests in a publicly traded security or mutual fund, held by a physician or an immediate family member, in the Covered Manufacturer or group purchasing organization during the preceding year.[10] Such disclosure must include the dollar amount invested by the physician, the value and terms of each such investment interest, and any payment or transfers of value to the physician holding an ownership or investment interest.

Pursuant to the Sunshine Law, Covered Manufacturers must report to HHS any payment or transfer of value made to a physician or teaching hospital, including detailed information about the nature and value of remuneration provided.

Evaluating the Implications for Providers

Disclosure of industry Payments to physicians and teaching hospitals poses several distinct risks. Information disclosed may be pertinent to a violation of fraud and abuse laws, to non-compliance with federal regulations on conflicts in clinical research, or may present a reputational risk due to the appearance of impropriety, even if the payment or other financial relationship with a Covered Manufacturer has not influenced medical practice by the physician or his or her affiliated institution. Moreover, Payments to physicians may prompt an inquiry into patterns and practices related to delivery and billing for services paid for by federal and state healthcare programs at institutions where physicians practice. For this reason, while teaching hospitals have the most significant exposure under the Sunshine Law, all healthcare providers that employ or contract with physicians in a position to shape purchasing or prescribing practices should consider the potential risks of transparency in payments by industry.

Fraud and Abuse Risks

Payments to Physicians. Information disclosed under the Sunshine Law, covering both Payments to physicians as well as physicians' investment and ownership interests, may trigger investigation of potential violations under the Anti-Kickback Law, False Claims Act, and the Stark Law. Federal and state anti-kickback laws bar the offer, provision or receipt of remuneration of any kind to an individual or entity to induce or in exchange for the referral of goods or services that are funded by the U.S. government or a state healthcare program (e.g., Medicare or Medicaid).[11] Payments to physicians for speaking, travel, consulting, and other services may violate the Anti-Kickback Law if any one purpose of the Payment is to induce physicians to prescribe medication or refer the patients for goods or services paid for by Medicare or Medicaid.[12] Federal

prosecutors and state attorneys general have prosecuted pharmaceutical and device companies for paying kickbacks to physicians in the form of consulting and speaking fees, meals and travel, and royalty payments, among other benefits conferred; settlement awards have reached billions of dollars and left many pharmaceutical and device companies with onerous reporting obligations under Corporate Integrity Agreements.[13]

Physicians who receive large Payments from pharmaceutical, device, or medical supply manufacturers, either from one company or in the aggregate relative to their peers, are most likely to prompt further scrutiny for potential kickback violations. Moreover, a high volume of procedures performed or prescriptions of high cost medications coupled with industry Payments may call into question the medical necessity of treatment provided, leading to the risk of an investigation for violation of the False Claims Act against physicians and/or their affiliated institution. Under the PPACA, violations of the Anti-Kickback Law can serve as the basis for False Claims Act violations for all claims submitted that resulted from illegal remuneration.[14]

The Stark Law prohibits physicians from referring Medicare beneficiaries to entities in which they, or their immediate family members, have a financial relationship, for certain services, including clinical laboratory services, physical and occupational therapy, durable medical equipment, prosthetic devices, and parenteral and enteral nutrients, unless an exception to the law applies.[15] Public disclosure of physician investment or ownership interests in a pharmaceutical, medical device, and medical supply company will create a road map for Stark Law enforcement.

Data mining also is likely to extend the scope of scrutiny by prosecutors and the press following disclosure of Payments to physicians and teaching hospitals. Prosecutors can be expected to use information about Payments to physicians as a starting point for data mining and analysis of claims tied to physicians for procedures and prescriptions, including the number of surgeries conducted, and prescriptions for off-label use of medications or high cost drugs. A recent front page story in the *Wall Street Journal* exemplified this kind of analysis.[16] Relying on publicly disclosed payments to orthopedic surgeons as well as mining of Medicare claims data, the article linked payments by orthopedic companies to spinal surgeons with the number of spinal fusion procedures the surgeons conducted, noting five surgeons at a hospital with the third highest rate of spinal fusion procedures in the nation had received more than $7 million from a manufacturer of devices used in the procedure. As demonstrated by other recent press articles covering payments to physicians, this kind of analysis also may lead to serious questions regarding quality of care due to invasive, unnecessary procedures.[17]

Through risk assessment and mitigation as well as policy development, healthcare providers can prepare for transparency in industry payments to physicians and teaching hospitals, rather than simply wait to see how prosecutors and the press will use the information disclosed.

Payments to Teaching Hospitals. Payments by pharmaceutical, device, and medical supply companies to teaching hospitals for a wide array of purposes, including clinical research, continuing medical education, and other grants, equity interests, royalty payments, and gifts, also will be disclosed under the Sunshine Law. As major purchasers of drugs, devices, and medical supplies, teaching hospitals also may violate the Anti-Kickback Law if Payments by industry are tied to referral of patients to particular drugs, devices, or supplies through the institution's purchasing decisions. For this reason, Pharmacy and Therapeutics Committees should operate with a strict conflicts of interest policy to assure that Payments from industry to individuals on the Committee or to the institution cannot in practice or perception influence purchasing decisions. Decisions by senior officials, including executives, Deans and Department Chairs, also may influence utilization of products and services, and therefore may be scrutinized if those individuals receive significant payment for services or have a license or equity interest related to drugs, devices, or other medical supplies utilized by or the subject of research at the institution.

Compliance with Federal Regulations on Conflicts of Interest in Research

Federal regulations require institutions that receive funding from the Public Health Service (PHS), including all National Institutes of Health, to identify and manage the financial interests of investigators in companies and products in which they or immediate family members have a financial interest

determined to be a conflict of interest.[18] Under current federal regulations, institutions must report only that a conflict exists and certify that they are managing the conflict. Regulations proposed in May 2010 would substantially increase the responsibility of institutions to report and manage conflicts of interest, requiring that for each conflict identified, the institution report to the funding PHS entity the nature of the conflict, the amount of the investigator's financial interest, and the facility's plan to manage the conflict.[19] As evidenced by congressional investigations of researchers at prominent universities, the Sunshine Law will intensify scrutiny of compliance with federal regulations that govern conflicts of interest in research.[20] Moreover, disclosure of financial relationships with industry also may heighten the risk of lawsuits and liability in the context of research and treatment. Specifically, research participants have sued for fraud and failure to provide informed consent when investigators and research institutions did not disclose their financial interests in the product under investigation. In one prominent case, involving Jesse Gelsinger, an 18-year-old healthy volunteer who died as a result of participation in a Phase I gene therapy trial, his father sued the researchers, the hospital that employed them, and the university that sponsored the trial for fraud, based in part on the failure to disclose the substantial equity stake held by both the investigators and the university conducting the trial. The widespread failure of certain devices also may prompt similar claims by plaintiffs apprised through the Sunshine Law of a financial relationship between their physician and a Covered Manufacturer.

Reputational Risk

Finally, apart from the risk of legal or regulatory violations, the disclosure of Payments to physicians and teaching hospitals presents significant reputational risks. While prosecutors have tended to pursue pharmaceutical and device manufacturers in kickback cases due to the huge financial penalties that can result, the press has focused on physicians. In the arena of reputational risk, physicians, teaching hospitals, and other providers should evaluate both actual conflicts and the appearance of conflicts, recognizing that the information, once in the public domain, can be freely used. Here too, physicians and teaching hospitals must consider how the information on Payments can be combined with other public data. For example, drawing upon public disclosure of payments to orthopedic surgeons, a recent well-publicized study found nearly half the surgeons paid anywhere from $1 million to $8.8 million dollars by companies that manufacture orthopedic devices had failed to disclose the payments as authors of medical journal articles related to the devices, in violation of the journals' conflict of interest policies.[21]

Preparing for Disclosure

Physician practice groups, hospitals, and other healthcare providers should prepare for public disclosure of Payments to physicians and teaching hospitals. Although HHS will not post the data on a public website until September 2013, the trigger date for data that will be reported is January 1, 2012. Physicians and facilities should conduct a risk assessment, starting with a judgment about the information they need to collect to identify and manage their risks. Some health systems and academic medical centers already have policies in place that require physicians to report information about payments from industry, as well as equity and other financial interests. For large physician practices and institutions, collecting information from all physicians with respect to the wide array of payment and ownership arrangements with pharmaceutical, device, and medical supply companies would be a significant administrative undertaking. Physician groups, facilities, and other providers therefore may choose to focus on areas they identify as high risk. Payments to physicians on the Pharmacy and Therapeutics Committee, the conflicts policy for the Committee, and adherence to the conflicts policy should be one priority. Other potential high-risk areas include Payments to physicians in executive positions and physicians who are high-volume providers. In the realm of clinical research, facilities should check compliance with existing federal regulations and prepare for more stringent identification and management of conflicts of interest under proposed new regulations.

In addition to internal compliance efforts to identify and remediate risk, physician practice groups, teaching hospitals, and other providers also should develop policies, if they have not done so already, that spell out the kinds of conflicts that will not be permitted, and limitations or management of other conflicts. Prominent large academic medical centers, partly in response to regulatory scrutiny, have developed extensive policies that address issues such as: limits on physician participation in speakers bureaus; acceptance of product samples; provision of meals onsite; continuing medical education grants; access by industry representatives to the site and staff; and policies that establish a rigorous process to identify and manage conflicts of interest in research.

For all providers, development of policies presents the opportunity to take a consistent, proactive approach to potential regulatory violations, conflicts of interest, and reputational risk. Through risk assessment and mitigation as well as policy development, healthcare providers can prepare for transparency in industry payments to physicians and teaching hospitals, rather than simply wait to see how prosecutors and the press will use the information disclosed.

About the Author

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End Notes

1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (hereinafter cited as PPACA), § 6402.
2. *Id.* § 6002.
3. Charles Ornstein *et al., Dollars for Docs Payments Approach $300 Million,* ProPublica (Dec. 22, 2010), *available at* http://www.propublica.org/article/dollars-for-docs-payments-approach-300-million (last visited July 1, 2011).
4. Barry Meier, *Tipping the Odds for a Maker of Heart Transplants,* N.Y. Times, Apr. 2, 2011, at A1; Barry Meier, *Inquiry into Payments by Drug Maker,* N.Y. Times, Apr. 6, 2011, at B2; Gardiner Harris, *Top Psychiatrist Didn't Report Drug Maker Pay*, N.Y. Times, Oct. 4, 2008, at A1.
5. Investigations at several major academic medical centers found prominent researchers had failed to disclose payments they received from pharmaceutical companies to their own universities, leaving the institutions subject to regulatory penalties. Jacob Goldstein, *Grassley Says Emory Psychiatrist Didn't Report $500,000 in Payments*, Wall St. J. Health Blog, Oct. 3, 2008; Jacob Goldstein, *University of Cincinnati Psychiatrist Under More Scrutiny Over Funding*, Wall St. J. Health Blog, Apr. 21, 2008.
6. Eric Campbell, *et al., Institutional Academic-Industry Relationships*, JAMA 298, No. 15: 1779-1786 (Mar. 7, 2007). Another study of 3,197 physicians found 94% reported some financial relationship with the pharmaceutical industry, with 78% receiving samples, 35% reporting reimbursement for professional meetings, and one quarter receiving payments for consulting, speaking, or enrolling patients in clinical research. Eric Campbell, *et al., A National Survey of Physician-Industry Relationships*, 356 N. Eng. J. Med. 1742-1750 (Apr. 26, 2007).
7. *See* James Sheehan, *How Payment Disclosure in Pharma and Devices Will Change Medicare/Medicaid Enforcement and Compliance*, 2d Annual Summit on Disclosure (Mar. 4, 2010), *available at* http://www.omig.ny.gov/data/content/blogsection/22/203/.
8. PPACA, § 6002(a).
9. *Id.*
10. *Id.*
11. *See, e.g.*, 42 U.S.C. § 1320a-7b.
12. *United States v. Greber*, 760 F.2d 68, 69-70 (3d Cir. 1985).
13. *See* http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp.
14. PPACA, § 6402.
15. 42 U.S.C. § 1395 nn.
16. John Carreyrou & Tom McGinty, *Secrets of the System; Top Spine Surgeons Reap Royalties Medicare Bounty*, Wall St. J., Dec. 20, 2010, at A1.
17. John Carreyrou, *Senators Request Probe of Surgeons*, Wall St. J., June 9, 2011, at A5.
18. 42 C.F.R. pt. 50 (2000).

Information disclosed may be pertinent to a violation of fraud and abuse laws, to non-compliance with federal regulations on conflicts in clinical research, or may present a reputational risk due to the appearance of impropriety, even if the payment or other financial relationship with a Covered Manufacturer has not influenced medical practice by the physician or his or her affiliated institution.

19. 75 Fed. Reg. 28688 (May 21, 2010). On May 24, 2011, the Food and Drug Administration (FDA) issued a draft guidance on reporting of information about clinical investigators' financial interests by trial sponsors, expanding the obligations from prior guidance issued and signaling that the FDA is likely to disclose the information publicly. United States Food and Drug Administration, Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators (May 2011).
20. *E.g.*, following a congressional investigation, Senator Grassley maintained that three Harvard Medical School physicians who helped pioneer the use of psychiatric drugs for children had failed to report over $3.2 million of payments by pharmaceutical companies received while conducting federally funded research on the efficacy of treatments for certain conditions. Rob Waters, *Harvard Doctors Failed to Disclose Fees, Senator says*, Bloomberg News, June 8, 2008.
21. Susan Chimonas, *et al., From Disclosure to Transparency: The Use of Company Payment Data* (Sept. 14, 2010), *available at* http://archinte.ama-assn.org (last visited July 1, 2011).