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The Sunshine Act's Final Rule: The Challenges and Compliance Risks for Health Care Providers in an Era of Transparency

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On Feb. 1, the Centers for Medicare & Medicaid Services (CMS) released the long-awaited final rule to implement Section 6002 of the Patient Protection and Affordable Care Act (PPACA), commonly referred to as the Sunshine Act.[1] The Sunshine Act mandates public disclosure of payments and ''other transfers of value'' by pharmaceutical, device, biological, and medical supply companies to physicians and teaching hospitals for a wide array of purposes, including consulting, speaking engagements, advisory board service, travel, food, and clinical research.[2] The act also requires manufacturers covered by the act (applicable manufacturers) and group purchasing organizations (GPOs) to report certain physician ownership and investment interests. Released by CMS over a year late, the final rule requires applicable manufacturers to begin collecting data on Aug. 1, 2013, and to report the data to CMS by March 31, 2014.[3]

The final rule sets forth highly detailed reporting requirements, underscoring the challenges for both manufacturers and health care providers posed by the Sunshine Act. While manufacturers face the onerous task of reporting under the act, health care providers must prepare for the scrutiny by prosecutors and the press likely to follow Sunshine Act public disclosure. Indeed, disclosure of the payment information will create a powerful new tool for prosecutors pursuing compliance with federal and state fraud and abuse laws.[4] To date, information about payments by device and pharmaceutical manufacturers to physicians disclosed as a result of corporate integrity agreements, state disclosure laws, and congressional investigations has garnered widespread press attention.[5] Information about

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[1] *Final Rule—Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests,* 78 Fed. Reg. 9,458, 9,521 (Feb. 8, 2013), http://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf (hereinafter cited as *Final Rule—Sunshine Act).*

[2] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119 (2010), http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010), http://www.gpo.gov/fdsys/pkg/PLAW-111publ152/pdf/PLAW-111publ152.pdf (hereinafter cited as PPACA).

[3] The Sunshine Act required the Department of Health and Human Services (HHS) to release a final rule implementing its provisions by Oct. 1, 2011, with public disclosure to begin on Sept. 30, 2013. *Id.*

[4] *See* James Sheehan, *How Payment Disclosure in Pharma and Devices Will Change Medicare/Medicaid Enforcement and Compliance*, 2d Annual Summit on Disclosure (March 4, 2010), http://www.omig.state.ny.us/data/images/stories/presentations/3-4-10_summit_on_disclosure.pdf.

[5] 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 March 15, 2013); Barry Meier, *Tipping the Odds for a Maker of Heart Transplants. New York Times*, April 2, 2011, at A1, *available at* http://www.nytimes.com/2011/04/03/health/03implant.html?_r=1&; (last visited March 15, 2013); Barry Meier, *Inquiry into Payments by Drug Maker*, *New York Times*, April 6, 2011, at B2,

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payments to teaching hospitals, disclosed for the first time by the Sunshine Act, also will face public scrutiny. Health care providers should therefore understand the information that will be disclosed, the risks posed, and concrete steps they can take to prepare for transparency.

A. Reporting Obligations

Manufacturers Bound by Sunshine Act. Under the Sunshine Act, manufacturers of a drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) (covered products) that operate in the United States or in a U.S. territory, possession, or commonwealth are applicable manufacturers and must comply with the act's reporting obligations.[6] Entities under common ownership with an applicable manufacturer that assist the applicable manufacturer in marketing, selling, or distributing a covered product in the United States also are applicable manufacturers and must comply with the Sunshine Act. The final rule clarifies that hospitals and hospital-based entities, such as pharmacies, that manufacture a product solely for use by the hospital or the entity's patients, are not covered by the act as manufacturers.

Applicable manufacturers must report to CMS on an annual basis any ''payment or other transfer of value'' (payments) made to a physician or teaching hospital, including detailed information about the nature and value of remuneration provided during the prior calendar year. Covered products include drugs, devices, and biological or medical supplies reimbursed directly by the federal government or under a composite rate such as the hospital inpatient prospective payment system. The final rule defines covered products to exclude over-the-counter medications and biological products and medical devices that do not require premarket approval or notification to the FDA.[7] As a result, manufacturers that produce only those products fall outside the ambit of the Sunshine Act.

Defining Covered Recipients. Applicable manufacturers must report payments they make to ''physicians'' and ''teaching hospitals'' (covered recipients). The Sunshine Act defines physicians broadly to include doctors of medicine and osteopathy, as well as dentists, podiatrists, optometrists, and licensed chiropractors. Physicians employed by applicable manufacturers, medical residents, and nonphysician practitioners are excluded from the definition of ''physician.''[8] As defined in the final rule, ''teaching hospital'' is any hospital that receives direct or indirect graduate medical education payments from Medicare. CMS will list teaching hospitals that are covered recipients on a public website.

What Must Be Reported. With few specified exceptions, applicable manufacturers must report all remuneration to physicians and teaching hospitals, above the de minimis amount of $10 per payment or $100 in the aggregate for a calendar year.[9] Specifically, applicable manufacturers must report to CMS:

- the name of the physician or teaching hospital to which the payment was made;
- the business address of the physician or teaching hospital, and, if the recipient is a physician, the physician's specialty and National Provider Identifier (NPI);
- the amount and date(s) of the payment;
- 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);
- a description of the nature of the payment (*e.g.*, consulting fee, travel); and
- if the payment is related to marketing, education, or research specific to a particular drug, device, biological, or medical supply, the name of the product and National Drug Code, if any, and, in the case of medical supplies, the name or product category.

In addition to payments made directly by applicable manufacturers to a covered recipient, applicable manufacturers also must report payments made to an individual or institution at the request of or designated by a covered recipient; for example, payments donated to a charity at the direction of a physician or teaching hospital still must be reported as payments to the covered recipient directing the donation.

Applicable manufacturers must report payments by the ''nature'' of the activity in one of the following categories: (1) consulting fees; (2) compensation for services other than consulting; (3) honoraria; (4) gift, (5) entertainment, (6) food, (7) travel (including the specified destination), (8) education, (9) research, (10) charitable contribution, (11) royalty or license, (12) current or prospective ownership or investment interest, (13) compensation for serving as faculty or as a speaker for a noncertified or accredited continuing education program, (15) compensation as a faculty or speaker at certified or accredited continuing educational program,(16) grant; or (17) space rental or facility fees for events held at a teaching hospital site.[10] Payments must be separated by category and cannot be bundled. For example, if an applicable manufacturer pays a physician for meals, travel, and consulting in one trip, the payments must each be reported in distinct categories.

Research Payments. In response to strong public criticism of the proposed reporting structure in the proposed rule for research, CMS substantially revised these provisions which now require applicable manufacturers to report, in a separate format from other payments, the following information for each research payment: (1) name of entity or individual receiving the payment, and for teaching hospitals and other research entities the business address; (2) name of physicians re-

available at http://www.nytimes.com/2011/04/06/health/06implant.html?_r=0 (last visited March 15, 2013).

[6] *Final Rule—Sunshine Act*, 78 Fed. Reg. at 9,521 (42 C.F.R. § 403.900).

[7] *Id.*

[8] *Id.* at 9466-67.

[9] The Sunshine Act preempts state legislation and regulations that mandate disclosure of the same information reported under the Sunshine Act. Consistent with the Sunshine Act's preemption clause, pharmaceutical and device manufacturers subject to state reporting laws will have to file state reports for information that is not covered by the Sunshine Act.

[10] *Final Rule—Sunshine Act*, 78 Fed. Reg. at 9,524 (42 C.F.R. § 403.904).

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ceiving payments, and related information for them as covered recipients, including address, NPI, and specialty; (3) name of the study; (4) name of any related covered product; and (5) total amount of payments made. The final rule limits the research category to *bona fide* research activities, defined as clinical investigations that are subject to a research protocol *or* a written contract between an applicable manufacturer and a covered recipient conducting the research.

In order to maintain the confidentiality of proprietary information related to product development, the Sunshine Act allows a delay for public disclosure of payments by applicable manufacturers for product development and research for a potential new medical technology, drug, device, biological, or medical supply, or a new application of an existing product.[11] Applicable manufacturers must report payments for research in the same timeframe as other payments, but the information will not be disclosed to the public until the earlier of the approval, licensure, or clearance of the covered product by the FDA, or four calendar years after the date of payment; if applicable manufacturers do not advise CMS of the delay, CMS will disclose the payment information the following calendar year.

Exceptions to Reporting. Certain payments to physicians or teaching hospitals are excluded from the reporting obligation. For example, product samples intended for patient use, patient educational materials that directly benefit patients, in-kind items provided as charity care to patients, and the loan of a device for a trial period not to exceed 90 days, among other items, are excluded. Payments made indirectly to a covered recipient through a third party, where the applicable manufacturer is ''unaware'' of the identity of the covered recipient also are excluded from the reporting obligation.[12] Applicable manufacturers therefore must report payments made through third parties, such as professional associations, and patient and disease advocacy organizations to covered recipients, if the applicable manufacturer is aware of the covered recipient's identity.[13] Payments provided to a physician through a group practice should be reported solely as payments to the physician(s) who is the intended recipient.

Reporting Physician Ownership Interests. In addition to reporting payments made to physicians and teaching hospitals, applicable manufacturers as well as GPOs must report certain ownership or investment interests held by physicians or their immediate family members in the applicable manufacturer or GPO.[14] Required disclosures include stock (excluding interests held in a publicly traded security or mutual fund), stock options (other than those received as compensation until exercised), partnership shares, limited liability company memberships, and loans or other financial instruments secured by a portion of the entity's property or revenue. Disclosures must encompass interests held by a physician and his or her immediate family members, and must specify: (i) the name of the physician and whether the interest is held by an immediate family member; (ii) the physician's address, NPI number, and specialty; (iii) the dollar amount invested by the physician or immediate family members; (iv) the value and terms of each investment interest; and (v) any payment provided to a physician holding an ownership or investment interest.

Reporting and Public Disclosure. On June 30 of each year following Sunshine Act implementation, CMS is required to disclose reported information on a public website that is easily searchable by manufacturers, physicians, and teaching hospitals. Applicable manufacturers, covered recipients, GPOs, and physician investors and owners must have the opportunity to review and correct the information at least 45 days prior to the disclosure date. CMS will notify covered recipients of the information that will be disclosed through e-mail listserves, online postings, and directly by e-mail to teaching hospitals and physicians who register in advance with CMS. CMS strongly recommends that all covered recipients undertake such registration.

Physicians and teaching hospitals are responsible for informing an applicable manufacturer about any disagreement regarding the payments reported. At the end of the 45-day review period, applicable manufacturers will have an additional 15 days to correct any data for final submission. CMS will not arbitrate disputes about the reports; if a dispute cannot be resolved by the parties, CMS will disclose the payments as reported by the applicable manufacturer, but will mark the payments as ''disputed.'' Physicians and teaching hospitals can report disputes at any time after the 45-day review period, but any related changes may not be noted until the following calendar year.

B. Assessing the Risks of Transparency

Sunshine Act disclosure presents an array of risks for physicians, hospitals, and other health care providers. Although HHS will not post the data on a public website until June 2014, providers should keep in mind that as of Aug. 1, 2013, Applicable Manufacturers will begin collecting the information for public reporting that will be posted on the CMS website.

Compliance Risks

Information reported about payments to covered recipients as well as physicians' investment and ownership interests may present significant compliance risks for health care providers. Specifically, the information may trigger investigation of potential violations under the anti-kickback statute (AKS), False Claims Act (FCA), and the Stark law.[15] Health care providers should anticipate that the data released under the Sun-

[11] The delay for public disclosure does not apply to clinical investigations related to the new application of an existing product. *Id.* at 9527 (42 C.F.R. § 403.910).

[12] The *Final Rule—Sunshine Act* defines awareness as actual knowledge, deliberate ignorance, or willful disregard of the covered recipient's identity. *Id.* at 9,522 (42 C.F.R. § 403.902).

[13] 78 Fed. Reg. at 9,522, 9489-90 (42 C.F.R. § 403.904). Indirect payments to speakers at accredited continuing medical educational programs that meet specified criteria are an exception to the reporting obligation. 78 Fed. Reg. at 9,524 (42 C.F.R. § 403.904(g)).

[14] *Id.* at 9525 (42 C.F.R. § 403.906).

[15] Federal anti-kickback statute, 42 U.S.C. § 1320a-7b; False Claims Act, 31 U.S.C. § 3729. Health care providers also may face liability under the Stark law which bars physician self-referrals. 42 U.S.C. § 1395nn.

shine Act will be used by prosecutors together with data mining of other databases, including Medicare and Medicaid claims data, to target investigations and pursue potential violations.[16]

The Anti-Kickback Statute. Federal and state anti-kickback statutes bar the offer, provision or receipt of remuneration of any kind, directly or indirectly, 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 health care program (*e.g.*, Medicare or Medicaid).[17] Federal and state anti-kickback laws have been a powerful tool for U.S. attorneys and state attorneys general who have prosecuted device and pharmaceutical companies for paying kickbacks to physicians for a wide array of activities: consulting and speaking fees, meals and travel, research funding, and royalty payments, among other benefits conferred.[18] Payments to physicians for speaking, travel, consulting, and other services may violate the AKS if any one purpose of the payment is to induce physicians to prescribe medication or use a device or medical supply paid for by Medicare or Medicaid.[19] Physicians who receive large payments from applicable manufacturers either from one company or in the aggregate relative to their peers, are most likely to prompt further scrutiny for potential kickback violations.

The AKS includes a safe harbor for personal services that, among other elements, requires that the services be provided under a written contract for a period of at least one year, and that payments be set in advance and not dependent on the value or volume of referrals to any federal health care program.[20] Another core element of the safe harbor is that the payment must be ''fair market value.'' CMS has defined fair market value as compensation that would be determined as a result of bona fide bargaining between well-informed parties not otherwise in a position to generate business for the other party.[21] This definition provides little guidance for payments by applicable manufacturers to teaching hospitals and physicians precisely because the latter are in a position to refer business. Moreover, reliance on comparable transactions, or historic prices, a common valuation method, must be used cautiously since such valuations may have been tainted by past industry practices. Physicians who are most influential with their peers in changing physician prescribing practices, such as department chairs and lead researchers—often referred to as ''key opinion leaders''—generally are paid a premium for consulting, speaking, and other activities. The higher payments to them as well as what is often a more subjective valuation analysis may render these payments more susceptible to greater regulatory scrutiny.

Heightened False Claims Act Exposure. The False Claims Act establishes civil and criminal liability for knowingly presenting a false claim for payment to the federal or state government.[22] Section 6402 of the PPACA linked AKS and FCA violations by establishing that any claims submitted to federal health care programs that result from a kickback automatically would violate the FCA, with potential penalties up to three times the amount of each claim submitted and $11,000 per claim.[23] The result is significantly increased risk of liability under both the AKS and the FCA. Moreover, an individual or organization can be liable under the FCA for filing or causing another party to file a false claim for reimbursement to a federal health care program.[24] Therefore, if payments by a manufacturer to a physician violate the AKS, the physician may also face liability under the FCA for the hospital's claims submitted to Medicare for medical services performed in connection with the product or device. In addition, 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 FCA against physicians and/or their affiliated institution.

Stark Law Exposure. 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.[25] 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.

Risks Arising From Research Payments. In the context of medical research, the Sunshine Act is one of several new regulations to seek transparency in payments by manufacturers. It follows on the heels of the final rule for conflicts of interest in research (final conflicts rule), adopted by HHS in 2011, which applies to all institutions that receive research funds from the National Institutes of Health (NIH).[26] The final conflicts rule sub-

[16] Through the Heat Project, federal agencies are collaborating on data sharing and mining and analysis to combat fraud. *See statement by William Corr, ''Efforts to Combat Health Care Fraud and Abuse,'' March 2010,* http://www.hhs.gov/asl/testify/2010/03/t20100304a.html. Journalists also have used data mining to analyze publicly disclosed payments to physicians. A Dec. 20, 2010, *Wall Street Journal* article linked payments to spinal surgeons with the number of spinal fusion procedures conducted, noting that 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. John Carreyrou and Tom McGinty, *Secrets of the System—Top Spine Surgeons Reap Royalties, Medicare Bounty*, *Wall Street Journal*, Dec. 20, 2010, at A1, *available at* http://online.wsj.com/article/SB10001424052748703395204576024023361023138.html (last visited March 15, 2013).

[17] 42 U.S.C. § 1320a-7b(b).

[18] *See* HHS OIG, Corporate Integrity Agreements, http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp. Settlement awards have reached billions of dollars and left many pharmaceutical and device companies with onerous reporting obligations under corporate integrity agreements.

[19] *United States v. Greber*, 760 F.2d 68, 69-70 (3d Cir. 1985).

[20] 42 C.F.R. § 1001.952(d).

[21] 42 C.F.R. § 411.351.

[22] 31 U.S.C. § 3729(a).

[23] PPACA § 6402(f)-(h).

[24] 31 U.S.C. § 3729(a); *see, e.g., United States v. Bornstein*, 423 U.S. 303, 313 (1976).

[25] 42 U.S.C. § 1395nn.

[26] *Final Rule—Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Fund-*

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stantially increased the obligations of investigators to report financial interests to their institutions and the duty of institutions to identify, manage, and publicly disclose interests determined to be a conflict of interest. For the first time, institutions must report specific information about such interests to NIH, along with a plan to manage the conflict, and make information available to members of the public, on request.

While the Sunshine Act delays the release of information about research payments at the election of applicable manufacturers, the act will disclose far more information about payments by applicable manufacturers than the final conflicts rule. In particular, the Sunshine Act will disclose information about all payments, not just those that pose a conflict with NIH-funded research, payments above a de minimis threshold of $10 in contrast to $5,000 under the final conflicts rule, and information about payments to teaching hospitals as well as physicians. Significantly, for institutions bound by the final conflicts rule, the Sunshine Act will provide an independent database for regulators to determine compliance with their obligations under the final conflicts rule.

For physicians who receive research funds independent of institutions bound by the final conflicts rule, the Sunshine Act poses distinct compliance risks. In particular, industry-funded research has been the target of increasing oversight by federal and state regulators, focused on compliance with the AKS and financial incentives that may present a direct conflict or risk to the interests of research participants. Physicians who conduct research in a group or private practice do not have the oversight provided by institutions that must comply with the final conflicts rule or internal institutional review boards that may scrutinize payments to investigators as part of protocol review.

For institutions as well as physicians in private practice, disclosure of research payments may also open the door to potential litigation by research participants harmed during clinical trials. In several prominent cases, plaintiffs have sued for failure to provide informed consent arising from undisclosed equity and other interests held by investigators and research institutions.[27] Some institutions, either as a result of institutional policies, IRB review, or a plan to manage identified conflicts of interest, already disclose payments by life science companies to research participants in the informed consent process.[28]

Institutional Conflicts of Interest. The final conflicts rule governs conflicts of interest by investigators, but not institutions. Moreover, as noted above, payments to teaching hospitals have not been publicly disclosed previously. For both these reasons, teaching hospitals may not have focused yet on identifying and managing institutional financial interests likely to receive significant public scrutiny following Sunshine Act disclosure.

Institutional financial interests arising from payments by applicable manufacturers can take a number of forms: equity in nonpublicly held companies, royalty payments to the institution, research and nonresearch grants, funding for continuing medical education, gifts, and the financial interests held by individuals in a position to influence purchasing or research decisions at the institution, including executives, department chairs, and deans. Both the American Association of Medical Colleges and the Association of American Universities have strongly advised institutions to develop written policies and procedures to identify, and manage institutional conflicts of interest, especially for research involving human subjects.[29] However, a 2011 study by the HHS Office of Inspector General found that many institutions still lagged in addressing institutional conflicts: in that study of 156 universities, medical schools, and other institutions that receive NIH funds for research, fewer than half had written policies or procedures that govern institutional conflicts of interest, suggesting a significant potential vulnerability for Sunshine Act disclosure.[30]

Payments to executives, department chairs, and other physicians in senior positions at teaching hospitals may present risks related to conflicts of interest as well as reputational risks, arising from significant payments by applicable manufacturers or management ties. In some states, such as New York, where both government and media attention have focused extensively on compensation for executives of not-for-profit providers, Sunshine Act disclosure may contribute to this already intensive public scrutiny.[31]

As major purchasers of drugs, devices, and medical supplies, teaching hospitals should review the practices and policies for their pharmacy and therapeutics committees since payments to physicians who serve on the committees may present significant compliance risks and conflicts.[32] Teaching hospitals as well as other pro-

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ing is Sought and Responsible Prospective Contractors on Research Conflicts, 76 Fed. Reg. 53,256, 53,283 (Aug. 25, 2011), http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf (hereinafter cited as *Final Rule on Research Conflicts*).

[27] In the most prominent case, involving Jesse Gelsinger, an 18-year-old healthy volunteer who died in a Phase 1 gene therapy trial, his parents sued the investigators, the research institute and the university that approved and sponsored the trial. *Complaint, Gelsinger v. Trustees of the University of Pa., No. 000901885 (Pa. Ct. Com. Pl., Sept. 18, 2000)*.

[28] The *Final Rule on Research Conflicts* identifies disclosure to participants as one alternative to manage conflicts of interest. 76 Fed. Reg. at 53,286 (42 C.F.R. § 50.605(a)).

[29] AAMC-AAU Advisory Comm. on Fin. Conflicts of Interest, *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research* 9 (Feb. 2008), *available at* https://members.aamc.org/eweb/upload/Protecting%20Patients,%20Preserving%20Integrity.pdf (last visited March 15, 2013).

[30] HHS OIG, *Institutional Conflicts of Interest at NIH Institutions* (January 2011), https://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf.

[31] *See Proposed Regulations—Limits on Executive Compensation and Administrative Expenses in Agency Procurements* (Oct. 31, 2012), http://www.humanservicescouncil.org/documents/Exec%20Order%20Regs%2038%2010-31-12.pdf (proposed New York state regulations limiting the compensation of executives at health care provider organizations); *see, e.g.*, Jim Dwyer, *For Some, Budget Pain Doesn't Hurt, New York Times*, Aug. 12, 2011, at A17, *available at* http://www.nytimes.com/2011/08/12/nyregion/fiscal-austerity-creates-pain-for-some-but-not-all.html?_r=0 (last visited March 15, 2013).

[32] A recent report highlighted the limitations in reporting and oversight of members of pharmacy and therapeutic committees within health plans that oversee Part D formularies. *See* HHS OIG, *Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions* 18-21 (March 2013), https://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf.

viders that operate with a Pharmacy and Therapeutics Committee should therefore examine Payments to physician members of the Committee and assure that the Committee operates with a strict conflicts of interest policy.

C. Preparing for Disclosure

Hospitals, physician practice groups, and other health care providers should take proactive steps to prepare for Sunshine Act disclosure. In accordance with the final rule, covered recipients will have only 45 days to review information before it is disclosed on a public website. In order to review and dispute payments, teaching hospitals and physicians must have a database of their own for comparison.

Assessing Compliance Risks. Collecting data internally will enable health care providers to identify and mitigate or eliminate compliance risks. Providers should begin by focusing on high risk areas, such as particular medical specialties, key opinion leaders, or physicians known to have significant financial interaction with manufacturers, and should evaluate their procedures and standards to assure that payments are consistent with sound fair market value analysis.[33] Physician groups should assess payments for clinical research, an area likely to receive particular regulatory scrutiny, while institutions that receive NIH funds should review data that will be disclosed under the Sunshine Act to evaluate investigator compliance with reporting required by the final conflicts rule.

Adopting Policies. 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, identifying the kinds of conflicts that will not be permitted, and setting limits on certain financial interactions with applicable manufacturers. Partly in response to regulatory scrutiny, prominent large academic medical centers 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; and access by industry representatives to the site and staff.

Educating Physicians. Physicians, especially those outside large medical centers, may be unaware of the Sunshine Act, and may not fully appreciate the legal implications and potential risks the payments pose to them under the AKS, the FCA, and the Stark law. Indeed, a January 2013 survey found that more than half the physicians surveyed did not know that the Sunshine Act required public reporting of payments to them.[34] Teaching hospitals and physician practices should educate physicians about pending disclosure under the Sunshine Act and the compliance risks disclosure poses to them.

Reviewing Compliance Effectiveness. If Sunshine Act disclosure prompts an investigation of a particular payment or pattern of payments, regulators and prosecutors are likely to scrutinize a provider's overall compliance program—how well the provider has implemented the required elements of an effective compliance program as set forth in federal compliance guidance.[35] Under the 2012 Federal Sentencing Guidelines, an organization's compliance program, including oversight of the program by the governing body, will be assessed in setting the penalty for violations of criminal law.[36] In general, prosecutors will be strongly influenced as they determine settlement terms by whether a provider has an active compliance program or one that exists primarily on paper.

D. Conclusion

The Sunshine Act reflects government's mounting reliance on transparency as a key enforcement tool. Through risk assessment and mitigation, providers should prepare for transparency, rather than simply wait to see how prosecutors and regulators will use the information disclosed. In anticipation of Sunshine Act disclosure, teaching hospitals and physicians should also consider how the payments they accept from manufacturers will be seen through the lens of the press, the public, and their patients. Ultimately, providers must prepare for the reputational as well as the compliance risks that disclosure may pose.

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[33] Fair market value calculations should be based to the extent possible, on quantifiable factors such as the physician's years of experience, level of education, and remuneration in relation to geographic area and specialty. See, Andrea Ferrari, *et al.*, *Determining ''Fair Market Value'' for Physician Services; The New 'Big Question' for Life Sciences Companies*, 3(1) AHLA Life Scis. 9 (April 2009), *available at* http://www.hcfmv.com/Publicationpdf/AHLA_LifeSciences_0409.pdf (last visited March 15, 2013).

[34] Thomas Sullivan, *Physicians Payment Sunshine Act: Survey Shows Physicians Still Unaware of Regulations* (March 5, 2013), *available at* http://www.policymed.com/2013/03/physician-payment-sunshine-act-survey-shows-physicians-still-unaware-of-regulations.html (last visited March 15, 2013).

[35] The OIG has released numerous compliance guidance statements specific to providers. *See, e.g., Notice—Publication of the OIG Compliance Program Guidance for Hospitals*, 63 Fed. Reg. 8,987 (Feb. 23, 1998), https://oig.hhs.gov/authorities/docs/cpghosp.pdf.

[36] U.S. Sentencing Comm'n, *2012 Federal Sentencing Guidelines Manual* § 8B2.1 (Effective Compliance and Ethics Program) (Nov. 1, 2012), http://www.ussc.gov/Guidelines/2012_Guidelines/Manual_PDF/2012_Guidelines_Manual_Full.pdf.

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