An Analysis of the Proposed Rule to Implement the Sunshine Provisions of the Patient Protection and Affordable Care Act

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Introduction

On December 14, 2011, the Centers for Medicare and Medicaid Services (CMS) released the long-awaited proposed rule (Proposed Rule) to implement transparency provisions of the Patient Protection and Affordable Care Act (PPACA).\(^1\) Specifically, Section 6002 of the PPACA (Sunshine Act) mandates that pharmaceutical, device, biological, and medical supply companies report to CMS payments and other transfers


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of value made to physicians and teaching hospitals.\textsuperscript{2} Information provided to CMS will be disclosed on a public website searchable by manufacturer, physician, and teaching hospital name.

The Proposed Rule provides important guidance about which manufacturers must report under the Sunshine Act, the scope of information that will be reported, and how manufacturers must track and report the information. For teaching hospitals and physicians, the Proposed Rule provides concrete guidance about the information CMS will disclose on a public website regarding payments by manufacturers for a wide array of purposes, including consulting, speaking, research, travel, and service on advisory boards. Overall, the Proposed Rule underscores the breadth of transparency that manufacturers as well as teaching hospitals and physicians will face about their financial arrangements under Sunshine Act disclosure. As discussed further below, the information that will be disclosed potentially poses significant compliance risks for both manufacturers and healthcare providers under federal and state fraud and abuse laws. For teaching hospitals, the information also has direct implications for compliance oversight of the final rule on conflicts of interest in research (Final Conflicts Rule) issued by the U.S. Department of Health and Human Services (HHS); the database of disclosed payments will provide an independent source of information to assess compliance with the Final Conflicts Rule.\textsuperscript{3}

The Sunshine Act required HHS to promulgate regulations to implement the Act by October 1, 2011, with January 1, 2012, as the date that manufacturers would begin to collect the information for public reporting. Recognizing the delay in releasing the Proposed Rule and the time required for manufacturers to build tracking systems to report the data, CMS announced in the Proposed Rule that it is inclined to delay the


date for data collection from January 1, 2012, until ninety days following publication of the final rule. This allows manufacturers more time to prepare to collect the data in accord with the specifications of the Proposed Rule. It also affords manufacturers, teaching hospitals, and physicians additional time to assess the significant compliance risks that disclosure may present. While providing substantial, detailed guidance about many questions, the Proposed Rule seeks comments on numerous issues, leaving resolution open to further public comment and the provisions of the final rule. The comment period for the Proposed Rule ended on February 17, 2012.

The Reporting Obligation: Which Entities Must Report

The Sunshine Act specifies that pharmaceutical, device, biological, and medical supply companies that operate in the United States and whose products are covered by Medicare, Medicaid, or the Children’s Health Insurance Program (Covered Products) must report to HHS any payment or transfer of value made to a physician or teaching hospital. The Proposed Rule defines manufacturers covered under the Sunshine Act (Applicable Manufacturers) as: (1) any entity engaged in the “production, preparation, propagation, compounding, or conversion of a covered drug, device, biological or medical supply for sale or distribution in the United States or in a territory, possession, or commonwealth of the United States”; and (2) any entity under common ownership with such an entity that provides assistance or support to manufacture, market, sell, or distribute a Covered Product in the United States. CMS proposed defining “common ownership” as ownership of any portion of two or more entities by a single individual or entity, and sought comments on the definition.

The Proposed Rule clarifies that a manufacturer whose products are sold or distributed in the United States must report under the Sunshine Act, regardless of where the products are manufactured or where the manufacturer is incorporated or located. Applicable Manufacturers that hold U.S. Food and Drug Administration (FDA) approval,

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4 Proposed Rule, at 78743.
licensure, or clearance for a Covered Product also must report payment information to CMS, even if they contract out the physical production of the Covered Product to another company. The Proposed Rule also specifies that a manufacturer that sells or distributes at least one Covered Product in the United States is an Applicable Manufacturer, and must comply with the Sunshine Act, regardless of whether the payments or other transfers of value are associated with a Covered Product.

**Covered Products**

The reporting requirements cover payments by Applicable Manufacturers of a drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, whether the reimbursement is available directly or is part of a composite rate. The Proposed Rule limits the definition of a Covered Product to drugs and biological products that require a prescription and devices and medical supplies that require premarket approval by or notification to the FDA. Accordingly, Applicable Manufacturers that produce only over-the-counter drugs or biological products or devices exempt from pre-market notification would not be required to report under the Sunshine Act.

**Covered Recipients—Teaching Hospitals and Physicians**

Applicable Manufacturers must report payments and "other transfers of value" made to physicians and teaching hospitals (Covered Recipients). The Proposed Rule defines "physicians" to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors, and advises Applicable Manufacturers to use the National Plan & Provider Enumeration System to identify individual physicians and their National Provider Identifiers. As defined in the Proposed Rule, "teaching hospital" is a hospital that received direct or indirect graduate medical education (GME and IME)

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5 Id.
6 Proposed Rule, at 78745.
7 Id.
payments during the most recent year for which the information is available. CMS recognized this does not capture teaching hospitals with accredited residency programs that do not receive GME or IME payments, and sought comment on the definition. CMS will publish a list of covered teaching hospitals to facilitate identification by Applicable Manufacturers.

**The Reporting Obligation: Required Reports**

The Sunshine Act divides the transparency reporting requirements into two parts. First, Applicable Manufacturers must submit annually certain required information for “payments or other transfers of value” made to Covered Recipients during the course of the preceding calendar year (CY). Second, Applicable Manufacturers and Group Purchasing Organizations covered by the Sunshine Act (Applicable GPOs) also must disclose any “ownership or investment interests” in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physicians. The Proposed Rule defines “immediate family member” as: (1) spouse; (2) natural or adoptive parent, child, or sibling; (3) stepparent, stepchild, stepbrother, or stepsister; (4) father-, mother-, daughter-, son-, brother-, or sister-in-law; (5) grandparent or grandchild; and (6) spouse of a grandparent or grandchild.

**Reports on Payments or Other Transfers of Value**

The Proposed Rule broadly defines payments “or other transfers of value” to include all such payments and transfers provided to a Covered Recipient, regardless of whether requested specifically by the Covered Recipient. Applicable Manufacturers must report charitable contributions and other payments or transfers made at the request of or on behalf of Covered Recipients. Moreover, any payments to a Covered Recipient made

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8 Id.
9 PPACA, § 1128G(a).
10 Proposed Rule, at 78752.
11 Proposed Rule, at 78743.
through a third party also must be reported, if the Applicable Manufacturer is aware of the Covered Recipient’s identity. As noted in the Proposed Rule, this means that if an Applicable Manufacturer provides a payment through a third party, such as a Continuing Medical Education provider or a specialty society to department chairs or other physicians at a specific hospital, the manufacturer must report the name of the third-party entity that received the payment directly, and the physician who received the payment(s) indirectly, if the manufacturer is aware of the physician’s identity. Additionally, CMS proposes that payments or transfers provided to a physician group or practice should be reported individually under the names of the physician-Covered Recipients.\(^{12}\)

The following table lists the specific categories of information that CMS proposes be reported for each payment or other transfer of value provided to a Covered Recipient.\(^{13}\) Categories of particular note or interest are discussed in greater detail below.

| Payments or Other Transfers of Value—Summary of Report Content Requirements |
|---|---|
| 1. Applicable Manufacturer or Applicable GPO name | 7. Name of the associated covered drug, device, biological, or medical supply (as applicable) |
| 2. Covered Recipient’s or physician owner’s (as applicable) | 8. Name of entity that received the payment or other transfer of value (if not provided to the covered recipient directly) |
| a. Name | 9. Whether the payment or other transfer of value was provided to a physician holding ownership or investment interests in the Applicable Manufacturer (Yes or No) |
| b. Specialty (physicians only) | 10. Whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation (Yes or No) |
| c. Business street address | |
| d. National Provider Identifier (NPI) (physicians only) | |
| 3. Amount of payment or other transfer of value in U.S. dollars | |
| 4. Date of payment or other transfer of value | |
| 5. Form of payment or other transfer of value | |
| 6. Nature of payment or other transfer of value | |

\(^{12}\) Id.

\(^{13}\) See Proposed Rule, at 78754.
-Date of Payment-

Under the Sunshine Act, Applicable Manufacturers must report to CMS the date upon which payments or other transfers are provided to Covered Recipients. For payments or transfers made over multiple dates, CMS proposes that Applicable Manufacturers may choose whether to report: (1) the total payment on the first date as a single line item; or (2) individual payments as separate line items.\textsuperscript{14}

-Associated Covered Drug, Device, Biological, or Medical Supply-

The Sunshine Act requires Applicable Manufacturers to report the name of the Covered Product associated with a payment or other transfer of value if it is related to “marketing, education, or research” of a particular covered drug, device, biological, or medical supply. The Proposed Rule provides that where a payment or transfer is \textit{reasonably associated} with a specific Covered Product, the name of the product (in the form of the name under which the product is marketed, where available) must be reported, but the Proposed Rule provides little guidance on how to determine when such an association exists.\textsuperscript{15}

-Form and Nature of Payment-

Applicable Manufacturers must identify \textit{both} the form and the nature of payment for \textit{each} payment or other transfer based on the specified categories. To avoid confusion, CMS proposes that Applicable Manufacturers: (1) select and report only \textit{one} category each for both the form of payment and the nature of payment; and (2) report separately all payments or transfers that fall within different categories, even where they are related.\textsuperscript{16}

\textsuperscript{14} Proposed Rule, at 78747.
\textsuperscript{15} Id.
\textsuperscript{16} Id.
With respect to the form of payment, the Proposed Rule directs Applicable Manufacturers to choose among the following categories: (1) cash or cash equivalent; (2) in-kind items or services; and (3) stock, stock options, or any other ownership interest, dividend, profit, or other return on investment. The Proposed Rule directs the use of the “dictionary definition” for these terms.

Under the Proposed Rule manufacturers must report the “nature” of payment in one of the delineated categories: (1) consulting fees; (2) compensation for services other than consulting; (3) honoraria; (4) gift; (5) entertainment; (6) food; (7) travel (including the specified destinations); (8) education; (9) research (discussed in greater detail below); (10) charitable contribution; (11) royalty or license; (12) current or prospective ownership or investment interest; (13) direct compensation for serving as faculty or as a speaker for a medical education program (CME); and (14) grant. CMS proposes that compensation for speaking be interpreted broadly beyond just those situations involving CME programs to encompass all instances in which Applicable Manufacturers pay physicians to serve as speakers.

-Special Rules for Research Payments-

CMS proposes to limit the research category to “bona fide” research activities, which would include clinical investigations subject to both a written agreement or contract between the Applicable Manufacturer and the organization conducting the research and a research protocol. The Proposed Rule outlines a proposed method for reporting research payments, recognizing that: (1) reporting payments or transfers for research activities may be complicated by the fact that many research activities include large payment amounts spread across numerous activities and parties; and (2) payments often are not provided directly to Covered Recipients, but to clinics, hospitals, or

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17 Id.
18 Proposed Rule, at 78748.
19 Id.
20 Proposed Rule, at 78750.
21 Proposed Rule, at 78749.
institutions administering the research that are in turn led by physician-Covered Recipients as the principal investigators (PIs).\textsuperscript{22}

The Proposed Rule distinguishes between “direct research” (where payments or transfers are provided directly to covered physicians or teaching hospitals) and “indirect research” (where payments or transfers are made to the organization conducting the research and then provided to physician-Covered Recipients acting as PIs).\textsuperscript{23} For both direct and indirect research, the Proposed Rule provides that payments or other transfers must be reported individually under the names and NPIs of physician-Covered Recipients serving as PIs.\textsuperscript{24} For indirect payments, Applicable Manufacturers must report both: (1) the name of the entity or individual that received the payment or transfer (reported as a direct research payment); and (2) assuming the Applicable Manufacturer is aware of the identity of the PIs, the physicians serving as PIs who ultimately received payments from clinics, hospitals, or other research institutions (reported as an indirect research payment).\textsuperscript{25} Moreover, for both direct and indirect research, Applicable Manufacturers must report the entire payment amount—rather than the specific amount—provided to the Covered Recipient for each research payment.\textsuperscript{26} However, for physician-Covered Recipients, CMS proposes that payments for research not be aggregated with other payments and transfers as disclosed on the public website.\textsuperscript{27} The Sunshine Act also provides for delayed publication of payments or other transfers of value made pursuant to product research or development agreements or clinical investigations, as discussed further below.

\textsuperscript{22} Id. \textsuperscript{23} Id. \textsuperscript{24} Id. \textsuperscript{25} Id. \textsuperscript{26} Id. \textsuperscript{27} Id.
**Exclusions**

The Sunshine Act excludes certain types of payments and transfers from the reporting and transparency requirements, including, among others, transfers of value less than $10 unless they aggregate above $100, and educational materials that directly benefit patients or are intended for patient use.\(^{28}\) Payments made indirectly to a Covered Recipient through a third party, where the Applicable Manufacturer is unaware of the Covered Recipient’s identity, also are excluded.\(^{29}\) Consistent with the “knowledge” standard set forth in the False Claims Act (FCA), CMS proposes that an Applicable Manufacturer will be deemed “aware” of a Covered Recipient’s identity if it has “actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient.”\(^{30}\) The Proposed Rule further states that awareness of the Covered Recipient’s identity by an agent of an Applicable Manufacturer is attributed to the Applicable Manufacturer.\(^{31}\)

**Reports on Physician Ownership or Investment Interests**

As previously noted, the Sunshine Act requires Applicable Manufacturers and Applicable GPOs to report certain information concerning: (1) ownership and investment interests held by physicians or their immediate family members in such Applicable Manufacturers and Applicable GPOs; and (2) payments or other transfers to such physician owners or investors. Given the overlap between the reporting requirements for payments or other transfers to physicians, and the reporting requirements for physician ownership and investment interests, CMS has proposed that Applicable Manufacturers may report payments and transfers under one category only, as discussed below.

\(^{28}\) See Proposed Rule, at 78750.  
\(^{29}\) Proposed Rule, at 78751.  
\(^{30}\) Id.  
\(^{31}\) Id.
**Applicable GPOs**

The Sunshine Act defines an Applicable GPO as an entity that purchases, arranges for, or negotiates the purchase of a Covered Product and operates in the United States, or in a territory, commonwealth, or possession of the United States. The Proposed Rule clarifies that the definition does not include entities that purchase Covered Products solely for their own use.\(^{32}\)

**Physician Ownership or Investment Interests**

CMS proposes that an “ownership or investment interest” should be defined in a manner similar to the physician self-referral regulation (i.e., the Stark Law).\(^{33}\) In particular, under the Proposed Rule, an interest may be direct or indirect, and may be debt, equity, or another form, including, but not limited to, stock, stock options, partnership shares, limited liability company memberships, loans, bonds, or other financial instruments secured with an entity’s property or revenue, or a portion of that property or revenue.\(^{34}\) In addition to the statutory exception for publicly traded securities or mutual funds, the Proposed Rule provides for the following three additional exclusions: (1) an interest in a retirement plan offered by an Applicable Manufacturer or an Applicable GPO; (2) stock options and convertible securities received as compensation, until the options are exercised or the securities are converted to equity; and (3) an unsecured loan subordinated to a credit facility.\(^{35}\)

\(^{32}\) *Id.*

\(^{33}\) *See* 42 C.F.R. § 411.354(b).

\(^{34}\) *Proposed Rule,* at 78752.

\(^{35}\) *Id.*
<table>
<thead>
<tr>
<th>For Applicable GPOs Only</th>
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<tr>
<td>For payments or transfers provided to physician owners or investors:</td>
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<tr>
<td>1. Amount of payment or other transfer of value in U.S. dollars</td>
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<tr>
<td>2. Date of payment or other transfer of value</td>
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<td>3. Form of payment or other transfer of value</td>
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<tr>
<td>4. Nature of payment or other transfer of value</td>
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<tr>
<td>5. Name of the associated covered drug, device, biological, or medical supply (as applicable)</td>
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To avoid duplicative reporting where there is overlap between physicians holding an ownership and investment interest and physicians who are Covered Recipients for the purposes of reporting payments or other transfers of value, the Proposed Rule states that Applicable Manufacturers should submit one file for all of their payments and transfers.\(^{36}\) Specifically, Applicable Manufacturers should: (1) report payments or transfers of value to physician owners or investors (regardless of whether the physician owner is a Covered Recipient) in the section for all payments and other transfers of value; and (2) note that the Covered Recipient receiving the payment or transfer is a physician owner or investor.\(^{37}\)

**Registration and Submission of Reports**

The Sunshine Act requires Applicable Manufacturers and Applicable GPOs to submit reports electronically to CMS on March 31, 2013 (for CY 2012), and on the ninetieth day of each subsequent calendar year. Applicable Manufacturers and Applicable GPOs may submit data prior to this date.\(^{38}\) CMS further proposes that: (1) Applicable Manufacturers and Applicable GPOs submit data electronically in a comma-separated value (CSV) format; and (2) the chief executive officer, chief financial officer, or chief compliance officer of the Applicable Manufacturer or Applicable GPO submit an attestation certifying...
that, to the best of his or her knowledge and belief, the data submitted are truthful, correct, and complete. Under the Proposed Rule, only Applicable Manufacturers that disclose payments or other transfers of value and/or physician ownership or investment interests for the previous calendar year must register and submit reports.

Public Disclosure

The Sunshine Act requires CMS to publish on a publicly available website the data reported by Applicable Manufacturers and GPOs for CY 2012 by September 30, 2013. For each year thereafter, CMS must publish the data for the preceding calendar year by June 30. The public website must be searchable by categories for Applicable Manufacturers, Applicable GPOs, physicians, and teaching hospitals, in a format that is clear and easily aggregated and downloadable.

The information on payments and other transfers disclosed on the website will include the following: (1) Applicable Manufacturer name; (2) Covered Recipient’s name, specialty (physician only), and business street address (practice location); (3) amount of payment or transfer in U.S. dollars; (4) date of payment or transfer; (5) form of payment or transfer; (6) nature of payment or transfer; (7) name of the Covered Product, when applicable; and (8) the name of entity that received the payment or transfer, if not provided to the Covered Recipient directly.

For physician ownership and investment interests, the following information will be disclosed on the website: (1) name of the Applicable Manufacturer or Applicable GPO; (2) physician owner’s name, specialty, and business street address; (3) whether the ownership or investment interest is held by the physician or an immediate family member.
member of the physician; (4) dollar amount invested; (5) value of terms of each
ownership or investment interest; and (6) any payment or other transfer of value
provided to the physician owner.\textsuperscript{44}

The CMS website also must include information about enforcement activities taken for
the previous year, and background or other helpful information on relationships between
the drug and device industry and physicians and teaching hospitals.\textsuperscript{45} In addition, CMS
proposes that the website clearly states that disclosure of a payment or other transfer
on the website does not indicate that the payment was legitimate nor does it necessarily
indicate a conflict of interest or any wrongdoing.\textsuperscript{46}

\textbf{Forty-Five-Day Review Period for Reported Information Prior to Disclosure}

Under the Sunshine Act, Applicable Manufacturers and GPOs, Covered Recipients, and
physician owners and investors must have forty-five days prior to public disclosure to
review and make corrections to the reported information.\textsuperscript{47} CMS proposes several
different ways for Covered Recipients to be informed of the process for reviewing
reported payment information: (1) Covered Recipients would be permitted, but not
required, to register with CMS; (2) CMS would post the information on its website or
publish in the \textit{Federal Register}; or (3) CMS would provide notice on its list serve.\textsuperscript{48}
The Proposed Rule sought comments on these alternatives.

CMS has stated that it will not arbitrate disputes that arise between Applicable
Manufacturers and Covered Recipients about the accuracy of the information reported,
but proposes that CMS would instead disclose the information from both parties in the
event a dispute cannot be resolved. Significantly, once the forty-five-day review period

\begin{footnotes}
\footnote{44}{Proposed Rule, at 78756.}
\footnote{45}{PPACA, § 1128G(c).}
\footnote{46}{Proposed Rule, at 78755-78756.}
\footnote{47}{PPACA, §1128G(c).}
\footnote{48}{Proposed Rule, at 78754-78755.}
\end{footnotes}
ends and the parties have identified all changes and disputes, CMS proposes that the reported data for that calendar year could not be amended further.49

Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations

Publication of payments or other transfers of value from Applicable Manufacturers to Covered Recipients for research and development of a new product will be delayed to maintain confidentiality of proprietary information.50 Specifically, publication of such payments and other transfers will be made publicly available after the earlier of either: (1) the approval, licensure, or clearance by FDA of the covered drug, device, biological, or medical supply; or (2) four calendar years after the date of payment.51 CMS proposes that Applicable Manufacturers must indicate on their report to CMS whether a payment or other transfer is eligible for delayed publication. Without this notification, CMS will post all payments in the following calendar year. Applicable Manufacturers must continue to specify in annual reports if FDA approval of the new drug, device, biological, or medical supply with which the payment is associated, is pending. Failure to notify CMS of FDA approval may be considered failure to report and may subject the Applicable Manufacturer to a civil monetary penalty (CMP).52

CMS proposes that payments or other transfers of value granted delayed publication should be limited to bona fide research or investigation activities pursued pursuant to a contract between the Applicable Manufacturer and Covered Recipient, as well as a written research protocol.53 If the Applicable Manufacturer contracts with a contract research organization (CRO), CMS proposes that delayed publication will apply if the CRO has a written research agreement with the Covered Recipient.54

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49 Id.
50 PPACA, § 1128G(c).
51 Id.
52 Proposed Rule, at 78770.
53 Proposed Rule, at 78756.
54 Proposed Rule, at 78757.
CMS proposes that delayed publication should apply to payments to Covered Recipients for services in connection with research on, or development of, new drugs, devices, biological, or medical supplies or a new application for an existing Covered Product as well as clinical investigations for new drugs, devices, biological, or medical supplies. CMS is considering whether delayed publication also should apply to payments in connection with clinical investigations related to new applications of existing Covered Products, and sought comment on this alternative.\(^{55}\)

**Penalties and Enforcement**

Any Applicable Manufacturer or Applicable GPO that fails to submit required information in a timely manner will be subject to a CMP.\(^{56}\) CMS proposes that, in addition to timeliness, a CMP may be imposed for failure to report information in an accurate and complete manner.\(^{57}\) A CMP of not less than $1,000, but not more than $10,000, may be imposed for each payment, transfer, or ownership or investment interest not reported, with the total CMP for each annual submission not to exceed $150,000. For a knowing\(^{58}\) failure to submit information, a CMP of not less than $10,000 and not more than $100,000 will be imposed for each payment, transfer, or ownership or investment interest not reported, with the total CMP for each annual submission not to exceed $1 million.\(^{59}\)

CMS proposes that the following factors be considered in setting the CMP amount:

1. the length of time the Applicable Manufacturer or GPO failed to report, including the length of time the Applicable Manufacturer and Applicable GPO knew of the payment or other transfer, or ownership or investment interest;
2. the amount of the payment, transfer, or ownership or investment interest not reported;
3. the level of culpability;
4. the nature and amount of information reported in error; and
5. the degree of

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\(^{55}\) Id.

\(^{56}\) PPACA, § 1128G(b).

\(^{57}\) Proposed Rule, at 78757.

\(^{58}\) As defined in the False Claims Act, 31 U.S.C. 3729(b).

\(^{59}\) Id.
diligence exercised in correcting information reported in error.\textsuperscript{60} In order to enforce the requirements set forth in the Sunshine Act, CMS proposes that HHS, CMS, the Office of Inspector General (OIG), or their designees may audit, inspect, or evaluate Applicable Manufacturers and GPOs for their compliance.\textsuperscript{61}

\textbf{Implications of Sunshine Act Disclosure}

\textit{Teaching Hospitals and Physicians: Assessing Fraud and Abuse, Research Compliance, and Liability Risks}

Information disclosed under the Sunshine Act has important implications for teaching hospitals and physicians with respect to fraud and abuse compliance, compliance with the Final Conflicts Rule for research, and potentially for malpractice liability as well. Information about payments and physician ownership and investment interests could trigger an investigation and lead to enforcement of the three major fraud and abuse laws; the Anti-Kickback Statute, the FCA, and the Stark Law. The risks under the Anti-Kickback Statute as well as the FCA must be assessed in light of the amendments to the Anti-Kickback Statute adopted by the PPACA. Under Section 6402 of the PPACA, claims submitted that are the result of a violation of the Anti-Kickback Statute are also a violation of the FCA, potentially extending the reach of FCA enforcement and penalties to claims submitted by physicians or teaching hospitals, with knowledge of an underlying kickback.\textsuperscript{62}

By disclosing payments that could constitute a conflict of interest for investigators that receive Public Health Service (PHS) funds for research, the Sunshine Act will provide an independent database for HHS and PHS to assess institutional compliance with the Final Conflicts Rule. It also will provide a tool for institutions to monitor compliance by their own investigators with the institutional reporting requirements mandated by the

\textsuperscript{60} Proposed Rule, at 78758.

\textsuperscript{61} \textit{Id.}

\textsuperscript{62} PPACA, § 6402(f).
Final Conflicts Rule. Finally, payment information under the Sunshine Act potentially has significant implications for quality oversight, patient safety, and malpractice. Disclosure of payments could lead to an inquiry about whether treatments provided were necessary and appropriate. Similarly, payment information may affect the trust that patients place in their physicians, and their willingness to bring suit in the event of a poor outcome involving the use of a covered drug, device, biological, or medical supply.

Compliance Risks for Applicable Manufacturers

The financial relationships reported under the Sunshine Act also could give rise to enhanced scrutiny and liability under the fraud and abuse laws for Applicable Manufacturers. For example, payments and other transfers above fair market value may lead to Anti-Kickback Statute and/or FCA liability. Notably, the government has recently secured several high-value settlements with pharmaceutical and medical device manufacturers due to allegedly unlawful financial relationships with physicians. Access to a new set of data with respect to industry-provider relationships could result in increased enforcement activity by OIG and the U.S. Department of Justice, and possibly an uptick in qui tam FCA cases.

Preparing for Transparency

Applicable Manufacturers as well as teaching hospitals, physician groups, and physicians that practice in other care delivery settings should seek to detect and correct potentially problematic financial relationships prior to disclosure under the sunshine Act. In this regard, pharmaceutical and medical device manufacturers as well as healthcare providers should consider conducting a “Sunshine Act compliance audit” to examine financial relationships from the perspective of fraud and abuse compliance, including the fair market value of payments and other transfers that will be disclosed, and then take any appropriate corrective action, such as modifying or terminating certain arrangements, prior to disclosure under the Sunshine Act. Such proactive compliance
efforts may reduce potential exposure to costly penalties, as well as expensive fraud and abuse investigations and FCA cases brought by the government or whistleblowers. Applicable Manufacturers as well as teaching hospitals may wish to consider the impact of the Sunshine Act on the disclosure provisions of clinical trial agreements. Those agreements may still be subject to other disclosure mandates under corporate integrity agreements, state sunshine laws, or FDA regulations, but the Sunshine Act may create more uniform expectations for disclosure. Physicians and teaching hospitals also may wish to consider development of comprehensive communications plans to explain the information that will be reported by CMS and the importance of the relationships reported to the advancement of science and the delivery of high-quality healthcare services.

Conclusion and Upcoming Program

CMS has not set a date for release of the final rule under the Sunshine Act. On Friday, March 9, the Conflicts of Interest and Transparency Affinity Group will host a roundtable discussion about the Proposed Rule with Niall Brennan, Director of the Policy and Data Analysis Group, in the Center for Strategic Planning at CMS. The audio program will be held from noon to 1:00 pm Eastern, and is open free of charge to all members of the Teaching Hospitals and Academic Medical Centers, Fraud and Abuse, and Life Sciences Groups. But, you need to [register](#) to listen in.