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PRACTICE RESOURCE

The Federal Sunshine Act: A Practice Guide

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Bradshaw and Kim: Federal Sunshine Act

Introduction

In the words of Justice Louis D. Brandeis, former Associate Justice on the Supreme Court of the United States, "Sunlight is said to be the best of disinfectants."[1] In that spirit, the federal Sunshine Act was created to ensure transparency in the financial relationships between the life sciences industry and certain healthcare professionals (HCPs) and organizations. It was introduced as part of the Patient Protection and Affordable Care Act (PPACA).[2] The regulations implementing the law became final on April 9, 2013, and life sciences companies are scrambling to comply with the first report submission deadline, March 31, 2014.[3]

This Practice Resource provides an overview of the Sunshine Act, beginning with the legislation's history; the who, what, when, and how of the law and its regulations; and necessary disclosure reports. We also include a list of resources, a discussion of several common compliance challenges, and a section on project planning and timing, including a functional checklist for managing a project of considerable size and scope.

The nuts and bolts of how compliance with the requirements transpires are organization-specific. For example, organization size, structure, operations, available resources, and budgets can shape Sunshine Act compliance efforts. Although we cannot address all potential regulatory challenges, we identify several that are typical across many pharmaceutical and medical devices companies.

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1 *See* Louis D. Brandeis Legacy Fund for Soc. Justice, Brandeis Univ., *Justice Louis D. Brandeis*, www.brandeis.edu/legacyfund/bio.html (last visited July 13, 2013).
2 Patient Protection and Affordable Care Act, Pub. L. No. 111-148 [hereinafter Patient Protection and Affordable Care Act].
3 42 C.F.R. pts. 402 & 403.

History

On March 23, 2010 President Obama signed PPACA, which included Section 6002, Transparency Reports and Reporting of Physician Ownership or Investment Interests.[4] The legislation was nicknamed the Sunshine Act because it was created to "shed light" on physician-industry financial relationships.

In a nutshell, the Sunshine Act requires "applicable manufacturers" of "covered drugs, devices, biological products, and medical supplies" to disclose annually certain information regarding "payments and other transfers of value" to "covered recipients," defined as physicians and teaching hospitals. An additional provision requires manufacturers and group purchasing organizations (GPOs) to disclose all ownership or investment interests held by physicians and members of their families. The information must be reported to the Centers for Medicare & Medicaid Services (CMS), the federal agency tasked with the law's implementation. CMS will then aggregate and post the information on a publicly searchable website. As a result, the public will have access to detailed financial information and a window into the healthcare industry's relationships with physicians. For example, patients will be able to search for information about their physicians and their relationships with a pharmaceutical company.

The who, what, when, and how

This Practice Resource focuses only on Applicable Manufacturers. This section provides a brief overview of the law and regulations. For more information, readers are referred to the final rules, which are complicated and granular.

4 Patient Protection and Affordable Care Act (codified at 42 U.S.C. § 1320a–7h).

Who are applicable manufacturers?

According to the regulations, an *applicable manufacturer* is an entity that is operating in the United States and falls within one of the following categories:

> (1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.
>
> (2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply.[5]

Common ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own five percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

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5 42 C.F.R. § 403.902.

An applicable manufacturer is defined as an entity "operating in the United States" if it

> (1) Has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or
>
> (2) Otherwise conducts activities within the United States or in a territory, possession or commonwealth of the United States, either directly or through a legally-authorized agent.[6]

Therefore, physical location is not dispositive. An entity outside the country may be operating in the United States by virtue of conducting activities (e.g., selling product) within the United States.

Who are covered recipients?

The law requires applicable manufacturers to report certain payments or transfers of value to covered recipients. The final regulations define a *covered recipient* as any physician (except for a physician who is a bona fide employee of the applicable manufacturer), or a teaching hospital that receives certain federal funds.[7] To minimize confusion, CMS will publish an annual list of teaching hospitals 90 days prior to the start of data collection. Physician types include doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors. The Sunshine Act does not apply to other HCPs such as nurse practitioners or pharmacists.

What is a covered product?

According to the final regulations, a *covered product* is any drug, device, biological or medical supply for which a payment is available under Medicaid, Medicare, or the Children's Health Insurance Program that

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6 *Id.* (emphasis added).
7 *Id.*

is reimbursed separately (such as through a fee schedule or formulary) or as part of a bundled payment. The products require either (i) a prescription to be dispensed or (ii) premarket approval or premarket notification to the Food and Drug Administration.[8] Most prescription products likely would be considered covered products under the Sunshine Act. An applicable manufacturer with one covered product must disclose all payments and transfers of value, whether related to covered products or not, except in certain limited circumstances.

What information must be reported?

The law and regulations specify the types of payments and transfers of value subject to disclosure, as well as the data elements required for each payment disclosed. At a high level, all payments and other transfers of value must be reported to CMS, unless specifically excluded from the reporting requirements. CMS has provided a list of categories to use when reporting non-research-related payments (research-related payments are reported separately, see below):

- Consulting fee
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
- Honoraria
- Gift
- Entertainment
- Food and beverage
- Travel and lodging (including the specified destinations)
- Education
- Charitable contribution

8 *Id.*

- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Grant
- Space rental or facility fees[9]

For each payment or transfer of value subject to disclosure, manufacturers must report many data elements, although the required data elements can vary depending on the type of payment. In general, each payment disclosure must include information about the recipient (physician or teaching hospital), including the name, business address, and specific identifiers, as well as payment information such as the date, value, form, and category (from the list above).

What are the exclusions?

The law and regulations provide several exemptions from the definition of "payment or other transfer of value." Exempt payments and transfers are not subject to disclosure. Exemptions include payments that are less than $10 (unless the aggregate for the year exceeds $100), product samples intended for patient use, loans of covered devices (not to exceed 90 days to permit covered recipient's evaluation), and discounts (including rebates). Educational materials that directly benefit patients or are intended for patient use also are excluded from reporting.[10]

9 *Id.* § 403.904 (e)(2).
10 *Id.* § 403.904(i).

What are the penalties for noncompliance?

The penalties for noncompliance apply equally across the board, whether the manufacturer has one covered product or many. The law states that a manufacturer that fails to submit information in a timely, accurate, or complete manner will be penalized $1,000 to $10,000 per item that is not reported, for a total penalty not to exceed $150,000 per reporting period. A manufacturer that *knowingly* fails to submit information will be penalized $10,000 to $100,000 per item that is not reported, for a total penalty not to exceed $1 million.[11]

When are the upcoming deadlines?

The important dates for manufacturers to note include the following:

- August 1, 2013: Data collection begins for reporting
- March 31, 2014: First reports to CMS due (for period August 1, 2013 to December 31, 2013)
- September 30, 2014: Data will be published online on CMS website
- April 1, 2015: CMS must provide its first reports to Congress

How must this information be reported?

CMS has provided applicable manufacturers with three report templates to submit payment and transfer of value disclosures and ownership or investment interest disclosures: the General Payments (Non-Research) Template, the Research Payment Template, and the Ownership/Investment Interest Template. The three templates distinguish among general payments, ownership interests, and payments related to research, such as funding for investigator-initiated studies and clinical trials. The templates provide detailed information on the required data elements and the data's exact format.

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11 *Id.* § 403.912.

CMS Resources

To provide guidance to life sciences companies and organizations tackling this new law, CMS has provided a number of resources on its website. In February 2013, CMS released the three draft report templates described above and also created the National Physician Payment Transparency Program: Open Payments website, which provides information about Sunshine Act requirements, fact sheets, tools, instructions, guidance, templates, and frequently asked questions (see Table 1 below). The Open Payments website is updated frequently with information on reporting, registration, and report submission.

Table 1. Open Payment Wesite Resources and URL Links

Open Payment Website Resource	URL
Information for Applicable Manufacturers	www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Applicable-Manufacturers-subpage.html
Information for Group Purchasing Organizations	www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Applicable-Group-Purchasing-Organizations-subpage.html
Physician Information	www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Physician-Subpage.html
Information for Teaching Hospitals	www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Teaching-Hospitals-subpage.html
Key Open Payment Activities	www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Key-OPEN-PAYMENTS-Activities.html
Frequently Asked Questions	www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/FAQs-Subpage.html
CMS Reporting Templates/ Specifications	www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10419.html

Compliance Challenges

As detailed and nuanced as the federal Sunshine Act is, the challenges with disclosure and reporting compliance are equally extensive. New and organization-specific challenges will emerge as the legal and technical requirements change, personnel leave or join the organization, and data are reviewed in a new light. This section discusses several challenges common across many manufacturing organizations.

Project ownership

It is critical that this disclosure and reporting project has an owner, because it stretches across departments within the organization, from Legal to Medical Affairs, from Marketing to Research and Development (R&D), with Information Technology (IT) and Finance as critical participants, as well as third-party vendors. This owner can be one person, or, as we recommend, a team that can manage a project of considerable size and make frequent decisions. The owner can and should delegate project tasks, but having an individual person or selected team with responsibility for the project plan, communication, and the outcome is critical to the project's success. Project Planning and Timing includes a discussion of the tasks and sub-projects that may be part of preparations for compliance. This section discusses the benefits of a project team, and some of the project owner's challenges.

The cross-functional team as an owner

Having a team of individuals with responsibility over the project's progress and success makes sense from both a substantive and logistical standpoint. Substantively, having input from individuals with insight into the organization's administrative and business sides helps in decision making. Logistically, each team member will have access to the organization's various areas and will have the opportunity to interact with individuals within the organization who have unique insights and

important points of view. For example, the head of the team may be from the Compliance Department, and team members often include an individual from Finance, Commercial/Sales Operations, and Marketing. Many organizations have added a team member from R&D to assist with the Sunshine Act's complicated research payment reporting requirements. Most successful teams also include at least one, and sometimes several, participants from the organization's IT group. Another consideration is including an attorney to make legal and interpretation decisions throughout the project; alternatively, without an attorney in the group, the team may maintain a list of questions and issues to be presented periodically to the organization's attorney.

Managing an unpopular project

Considering the breadth and risk associated with a disclosure and reporting compliance project, it is no wonder that it is often an unpopular one. The project is sizable—it requires gathering information from nearly every department of the organization. It often has a high profile with significant expectations from management and executives. The requirements may change mid-project—CMS continues to respond to questions from the industry and has not yet developed the technology and precise system processes for submitting, reviewing, and revising data. Updates may make it necessary to revisit legal analyses or return to vendors or internal departments and revise the data requirements previously demanded. Although the project may seem overwhelming, organizations should focus on the opportunities and organization-wide access that come from such a herculean endeavor. The owner, be it an individual or team, should present the project internally and externally as a way for the organization to gain new access and insight into information. The data may have been available within the organization, but this project requires pulling it together for disclosure and reporting purposes, providing observations into internal expenses, as well as organization-wide visibility.

Relationship management and customer communication

Although much of the disclosure and reporting project takes place internally, one of the results of the Sunshine Act will be public posting on a CMS website. That means that customers—the physicians and other covered recipients who purchase, use, or prescribe an organization's products—will be exposed publicly without their consent. Physicians' awareness and understanding of the Sunshine Act varies greatly, as do their reactions. Organizations must decide if they will educate their customers proactively, as well as whether they will provide data to covered recipients in advance of submission to CMS, as recommended by CMS but not required by the law. If the organization takes these proactive steps, how will they be effectuated? In Proactive communication? Reactive communication?, we discuss considerations for communication about disclosure data.

Proactive communication? Reactive communication?

A significant challenge for organizations engaging in proactive communication is determining who will be responsible for communication. Often, individuals in the field have the closest relationships with physicians. These communications are, of course, difficult to control and monitor. If the organization will provide data to covered recipients proactively, how will it be disseminated—electronically, by mail, in person? Will data be provided to all covered recipients, only physicians, or only certain physicians? For example, some organizations may choose to provide information relating to consulting arrangements—speaker fees, advisory board honoraria, clinical investigator milestone payments, travel reimbursements, and the like—rather than all data to every individual who has received a meal or textbook throughout the year. It is also necessary to consider the ability of organizational departments to convey the information. For example, it may not be appropriate for all correspondence to go through Sales Operations, but Compliance may not have the capacity to handle this initiative.

Organizations may select from a variety of approaches to proactive communication about the disclosure and reporting initiative. For example, an organization might provide information during the contracting process and in contracts with physicians and other covered recipients. An organization might proactively communicate with physicians on an ad hoc basis—at in-office meals, speaker programs or educational trainings, congresses, and the like. Engaging in those communications means careful delivery of information, or alternatively directing the physicians to call an organization's hotline or view an organization's website. The level of information may vary. For example, one organization may choose to provide a 3 x 5 card to each physician who interacts with a sales representative, and the card may state only the company's obligation to disclose to the government certain information about the physician and the interaction, directing any questions to a website or phone number. Providing information through field teams means that the organization must train sales representatives thoroughly on the information provided to physicians, on what the representatives may and may not discuss, and on the process for handling follow-up questions and any concerns. Another organization may choose to send letters or emails to each covered recipient with whom it has entered into a contract during the reporting period, outlining the Sunshine Act, the company's internal compliance and reporting processes and, again, providing contact information.

Another necessary decision in the organization's communication plan relates to releasing data to covered recipients and consultants before submitting the data to CMS. This could be on a periodic basis or once a year. In theory, this type of communication may help avoid post-submission disputes. A consideration, however, is ensuring that each communication is accurate and that the recipient has a venue to respond and discuss the data on an ongoing basis. Organizations will have to confirm that the information provided to each recipient includes all data for that recipient, ensuring that the picture presented

is complete and represents the information the recipient can expect to see on the CMS website. This means pulling data from the same system that must be queried to disclose the organization's financial system, as well as from third-party vendors, sales force systems, and expense reimbursement systems, and then aggregating it to create a user-friendly report. Organizations must be confident that the information does *not* include data for any other individual recipient. Even though the data eventually will be published publicly, some physicians, understandably, have privacy concerns about their information and their interactions with organizations in the life sciences industry.

Additionally, any organization engaging in proactive communication must have its dispute resolution process already established. Any covered recipient receiving the data likely will have questions about, if not challenges to, some of the information. To address these issues and have a meaningful pre-submission review process, the organization must be able to respond to the questions, review and update internal records, and provide proof of corrected data or an explanation why the information will not be changed. To effectuate the process, responsible personnel must be trained, and the organization must have a means of documenting disputes, changes, and responses for internal recordkeeping.

On the other end of the spectrum, organizations must determine how to handle post-disclosure communications. Unlike the voluntary pre-submission communication process, every organization must participate in the post-submission dispute resolution process. After organizations submit reports to CMS, but before data are published publicly, every physician and teaching hospital that has registered with CMS will have access to a secure site displaying data relating specifically to itself. These covered recipients will have time to review the data and challenge particular data submissions through specific dispute resolution procedures. This process will not be optional for organizations. If a physician or teaching hospital disagrees with an amount, a categori-

zation, or that an interaction occurred at all, it will be important both to maintain the relationship with the covered recipient and respect the integrity of the data. Organizations must have a process in place for receiving these disputes, reviewing the data and providing supporting materials to the recipient, and making updates to data internally before submitting reports to CMS. Having an individual or team well-versed on the law and regulations, familiar with the CMS guidance, and trained on internal procedures will help organizations to resolve disputes quickly and amicably.

Logistical compliance challenges

Not to be overlooked, logistical and operational issues can present significant challenges throughout the disclosure and reporting project. A few issues likely to arise in all organizations relate to the clinical data subject to disclosure, tracking and valuing educational materials, and meeting Sunshine Act requirements while not overlooking state reporting obligations.[12]

Research requirements and working with clinical research organizations

Until the Sunshine Act, research-related disclosures were limited. Just bringing the R&D or Clinical Operations department into the disclosure and reporting project may be met with resistance. In addition, clinical research may be handled internally, through agreements with clinical research organizations (CROs) or site management organizations (SMOs), or both. CROs and SMOs serve as important third-party organizations that manage entire clinical trials, or portions thereof,

12 The following states currently have disclosure laws: District of Columbia (D.C. Code §§ 48-833.01–.09); Massachusetts (Mass. Gen. Laws ch. 111N); Minnesota (Minn. Stat. § 151.47); Vermont (Vt. Stat. Ann. tit. 18, §§ 4631a, 4632); West Virginia (W. Va. Code § 16-29H-8).

and thus often have a significant amount of an organization's research-related payment information in their internal systems. Regardless of data ownership, the data required for disclosure to CMS, while less onerous than that proposed in the draft regulations, often are maintained in separate sources and cannot be formatted easily to comply with CMS's Research Report form. Many CROs have created formats in which they will provide data to manufacturers, but organizations should verify that the data and its format meet the organization's requirements. Any contract with a CRO, and those directly with trial sites, should include a provision acknowledging the obligation to disclose, and specify data and format requirements.

Valuing and tracking educational materials

Educational materials are subject to Sunshine Act disclosure unless exempted.[13] Specifically, excluded from reporting requirements are "educational materials and items that directly benefit patients or are intended to be used by or with patients."[14] First, an organization must evaluate its materials and determine what will be disclosed, and what will be excluded from the CMS submission. This alone can be a difficult decision. Once a decision has been made to report a particular item, the organization must determine the item's value and must establish a means to calculate and add tax and shipping costs when appropriate. Finally, some organizations currently do not track the dissemination of these materials. Some states allow reporting of certain materials in the aggregate—e.g., the value of all materials disseminated in Vermont[15]—but the Sunshine Act does not include this flexibility. Some companies

13 42 C.F.R. § 403.904.
14 *Id.*
15 *See* Vt. Office of the Attorney Gen., Guide to Vermont's Prescribed Products Gift Ban and Disclosure Law for 2013 Disclosures (2012), *available at* www.atg.state.vt.us/assets/files/2013%20Guide%20to%20Vermonts%20Prescribed%20Product%20Gift%20Ban%20and%20Disclosure%20Law.pdf (discussion of "Alternative Aggregate Disclosure" throughout).

may choose not to distribute any materials via sales representatives and instead send materials only on request or through a targeted mailing program, allowing straightforward tracking at dissemination. Another option is to build a tracking mechanism into the sales force automation (SFA) tool.

Complying with Sunshine and state requirements

Currently, the focus of most applicable manufacturers is on preparing for compliance with the Sunshine Act. Although this focus is critical, in no small part because of the public and governmental spotlight trained on national disclosure, it is important to remember that state obligations remain unless expressly preempted or repealed. The Minnesota legislature, for example, recently passed legislation revising disclosure obligations to acknowledge Sunshine Act preemption.[16] Of note, though, Minnesota did not repeal its gift ban law—organizations may only provide up to $50 in the aggregate to each prescriber annually.[17] Other states have acknowledged the federal requirements and stated that they will not repeal their laws but will make allowances or changes to comply with the Sunshine Act preemption provision.[18]

Ensuring that the organization is tracking spending at the necessary level of granularity to allow for compliance with *all* laws must be a meaningful component of the disclosure and reporting project. For example, the Sunshine Act requires reporting only on payments and transfers of value to physicians and teaching hospitals. Every state with a

16 Minn. Stat. § 151.47; *see also* Memorandum from Cody Wiberg, Exec. Dir., Minn. Bd. of Pharmacy, to Pharmaceutical Manufacturers and Drug Wholesalers Licensed by the Board (June 24, 2013), *available at* www.phcybrd.state.mn.us/Payments/MemopaymentJune2013.pdf.

17 Minn. Stat. § 151.461.

18 *See, e.g.*, Letter from Madeleine Biondolillo, Dir., Bureau of Health Care Safety & Quality, Exec. Office of Health & Human Servs., Commonwealth of Mass., to Pharmaceutical and Medical Device Manufacturers (Dec. 28, 2011), *available at* www.mass.gov/eohhs/docs/dph/quality/healthcare/pcoc/ma-pharm-code-of-conduct-circular-letter-12-28-2011.pdf.

disclosure law, however, has a "covered recipient" or "healthcare professional" definition broader than the Sunshine Act's requirements.[19] For example, some include nurse practitioners, employees of physicians, or clinics. Thus, vendors, field personnel, and internal departments must be aware of the organization's specific tracking requirements. In addition, for every data capture source, the organization must be able to comply with both the Sunshine Act and applicable state rules.

Project Planning and Timing

Planning to comply with Sunshine Act reporting is no small feat, and the path to compliance will be different for each organization. Among other things, it will depend on its type and size; its available resources, both people and funding; and, of course, its place in the grand scheme of disclosure and reporting compliance to date. Larger drug companies with a focus on compliance are generally farther along in the full disclosure and reporting compliance program and process, with teams already in place to handle state reporting and support from executives to facilitate Sunshine Act initiatives. Contrast this with many small device or start-up biotechnology companies where reporting is not yet a priority and budgets are extremely tight. Their project plans will look very different, and implementing a plan for compliance should be approached differently.

Creating a planning checklist

Generally, there are steps that any organization will take to ensure that the first year of Sunshine Act compliance proceeds as smoothly as possible. These steps are listed in Exhibit 1. Organizations already may have completed several of these tasks, but may not have considered

19 D.C. Code §§ 48-833.01–.09; Mass. Gen. Laws ch. 111N; Minn. Stat. § 151.47; Vt. Stat. Ann. tit. 18, §§ 4631a, 4632; W. Va. Code § 16-29H-8.

others at all. The order is flexible, too—for some organizations, it will make sense to perform the more process-focused steps first, and then turn to data; for others, the order provided here may be ideal. In reality, many tasks will occur simultaneously. Whichever items are on the list for a particular organization, it is critical to have a plan with set target dates and to meet regularly with the team and/or stakeholders to keep the project moving forward.

Exhibit 1. Functional Checklist for Project Planning

- ✔ Identify a project owner (or owners)
  - ✔ Identify individual or individuals with decision making authority
  - ✔ Create a Sunshine team, often cross-functional with members from IT, finance, sales operations, compliance or legal, medical, and/or R&D
- ✔ Document Sunshine Act requirements
  - ✔ Involves compliance and legal analysis of the law, regulations, and CMS guidance to make organization-specific interpretation decisions
  - ✔ Allows the organization to identify which interactions, payments, and other transfers of value will be disclosed, and what technical requirements are necessary for automated disclosure and reporting solutions
- ✔ Complete a thorough discovery of data and source systems to identify where Sunshine Act data may reside
  - ✔ Review internal sources (each department, each system) and identify external sources (each department's vendors)

Exhibit continues on next page.

- ✔ Identify each source's owner, who has responsibility for compliance with requirements and use
- ✔ Review sources to determine what information is present, what is available, and if necessary, what must be added or changed for each source
- ✔ Consider whether to use a third-party consultant to complete this discovery process

✔ Analyze and adjust the customer master (a master list of HCPs and organizations with which the organization interacts)

- ✔ As needed, create, purchase, or review and update the customer master
- ✔ Confirm data elements needed (National Provider Identifier, state license number, address, designation, specialty, etc.)
- ✔ Determine when and how to incorporate the customer master into the data sources identified during the discovery process

✔ Decide how to handle disclosure and reporting

- ✔ Decide whether to purchase a third-party tool, build a solution internally, or handle manually
- ✔ Identify who will manage the development and design process, and memorialize business requirements via business requirements sessions
- ✔ Facilitate the request for proposal and/or request for information process, if applicable

Exhibit continues on next page.

- ✔ Train individuals with HCP and healthcare organization (HCO) interactions
  - ✔ Ensure that individuals who interact with HCPs and/or HCOs—whether via grant requests, the invoicing process, at congresses and professional meetings, in the physician's office, etc.—understand the requirements and the practical implications
- ✔ Create a data monitoring and remediation process
  - ✔ Identify who will be responsible for ongoing support and ownership
  - ✔ Set a process for data monitoring and periodic audits
- ✔ Discuss the report creation and submission process
  - ✔ Determine a timeline, process, and responsible parties for reviewing data for completeness and accuracy, generating and verifying reports, and report submission
- ✔ Determine the communications to HCPs and the dispute process
  - ✔ Discuss proactive communications with physicians and teaching hospitals in advance of report submission, whether generally about the Sunshine Act requirements or specifically about the related data
  - ✔ Identify who will handle disputes, whether directly from HCPs/HCOs or through CMS's official process
- ✔ Create or update standard operating procedures (SOPs) and documentation processes
  - ✔ Ensure the processes described above are outlined clearly in SOPs or work instructions

Exhibit continues on next page.

- ✔ Determine how to memorialize assumptions and interpretations and whether to submit an assumptions document to CMS
- ✔ Document how and where data, correspondence, and reports will be archived

Conclusion

The Sunshine Act presents life sciences organizations with a complicated set of requirements for tracking and disclosing payments and other transfers of value made to physicians and teaching hospitals. Practically speaking, these requirements mean each organization must review its internal policies, procedures, and systems, as well as its interactions across the healthcare industry. At this time, the transparency initiative is, rightfully, a focus for many organizations and should continue to be a priority over the next year as they solidify their internal processes, prepare for data submission, and respond to public disclosure.